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

FORM 10-K

[X] Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2004

or

[ ] Transition Report pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission File Number 0-9314

ACCESS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	83-0221517
(State of Incorporation)	(I.R.S. Employer I.D. No.)

2600 Stemmons Freeway, Suite 176, Dallas, TX	75207
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: (214) 905-5100

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

Common Stock, One Cent ($0.01) Par Value Per Share	American Stock Exchange
(Title of Class)	(Name of each exchange on which registered)

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

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 [X] 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 Exchange Act Rule 12b-2). Yes [X] No [ ]

The aggregate market value of the outstanding voting stock held by non-affiliates of the registrant as of June 30, 2004 was approximately $85,395,000.

As of March 20, 2005 there were 15,524,734 shares of Access Pharmaceuticals, Inc. Common Stock issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of Registrant's Definitive Proxy Statement filed with the Commission pursuant to Regulation 14A in connection with the 2005 Annual Meeting are incorporated herein by reference into Part III of this report. Other references incorporated are listed in the exhibit list in Part IV of this report.

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PART I

ITEM 1. BUSINESS

This Form 10-K (including the information incorporated by reference) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties. These statements include without limitations statements relating to anticipated product approvals and timing thereof, the terms of future licensing arrangements, our ability to secure additional financing for our operations and our expected cash burn rate. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "expects," "plans," "could," "anticipates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of such terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under "Risk Factors," that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels or activity, performance or achievements expressed or implied by such forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We are under no duty to update any of the forward-looking statements after the date of filing this Form 10-K to conform such statements to actual results.

BUSINESS

Access Pharmaceuticals, Inc. (Access) is a Delaware corporation. We are an emerging pharmaceutical company focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities.

Together with our subsidiaries, we have proprietary patents or rights to seven drug delivery technology platforms:

- synthetic polymer targeted delivery,
- vitamin mediated targeted delivery
- vitamin mediated oral delivery,
- bioerodible cross-linker technology,
- mucoadhesive disc technology,
- hydrogel particle aggregate technology, and
- Resiferm(R) topical delivery.

In addition, we have acquired the amlexanox patents and technology for the treatment of mucosal and skin disorders.

We use our proprietary technology to develop products and product candidates. Our patents and trade secrets protect our marketed products, amlexanox 5% paste (marketed under the trade names Aphthasol(R) and Aptheal(R)) and Zindaclin(R), and our product candidates that are currently in the drug development phase, DACH platinum (AP 5346), polymer platinate (AP 5280) and OraDisc(TM).

We are marketing amlexanox 5% paste, the first U.S. Food and Drug Administration (FDA) approved product for the treatment of canker sores, under the trade name Aphthasol(R) in the United States. In September 2001, ProStrakan Limited, our United Kingdom partner, received marketing authorization to market amlexanox 5% paste in the U. K. under the trade name Aptheal(R). We have received marketing approval in 10 European Union countries following completion of the Mutual Recognition Procedure (MRP). Approval to market was granted in Austria, Germany, Greece, Finland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, and Sweden. We are developing new formulations and delivery forms of amlexanox, including mucoadhesive disc delivery. In 2004, we received approval of our new drug application for OraDisc(TM) A from the United States Food and Drug Administration (FDA). OraDisc(TM) A is an improved delivery system for amlexanox. The OraDisc(TM) technology is a proprietary mucoadhesive patch that gradually erodes and releases an active ingredient when applied to the inside of the mouth.

In addition, ProStrakan has used our patented Residerm(R) technology to develop a zinc clindamycin formulation for the treatment of acne. ProStrakan began marketing zinc clindamycin in the United Kingdom under the trade name

Zindaclin(R) in March 2002. The process to achieve marketing authorization for Zindaclin(R) throughout Europe has now been completed, with approvals in most European Union countries including the new member states and several non-European countries. We anticipate that in the next twelve months approvals will be obtained in additional other countries.

KEY DEVELOPMENTS

As of March 30, 2005 the Company executed a Standby Equity Distribution Agreement (SEDA) with Cornell Capital Partners. Under the SEDA, the Company may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to $15,000,000. The purchase price for the shares is equal to their market price, which is defined in the SEDA as 98% of the lowest volume weighted average price of the common stock during a specified period of trading days following the date notice is given by the Company that it desires to access the SEDA. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the Equity Line of Credit. The amount of each draw down is subject to a maximum amount of $1,000,000. The terms of the SEDA do not allow us to make any draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our outstanding shares of common stock. The Company believes that because of the ability of Cornell Capital to sell shares under a registration statement and as a result of Cornell Capital's business model Access does not believe that Cornell would accumulate 9.9% of the outstanding common stock of the Company. Upon closing of the transaction, Cornell Capital Partners will receive a one-time commitment fee of 146,500 shares of the Company's common stock. On the same date, the Company entered into a Placement Agent Agreement in escrow with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the Placement Agent Agreement, upon closing of the transaction the Company will pay a one-time placement agent fee of 3,500 shares of common stock.

In addition, as of March 30, 2005, the Company executed a Securities Purchase Agreement with Cornell Capital Partners and Highgate House Funds. Under the Securities Purchase Agreement, upon closing Cornell Capital Partners and Highgate House Funds are obligated to purchase an aggregate of $2,633,000 principal amount of Secured Convertible Debentures from the Company (net proceeds to the Company of $2,360,000). The Secured Convertible Debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the Secured Convertible Debenture has not been converted to common stock. The Secured Convertible Debenture is convertible into the Company's common stock at the holder's option any time up to maturity at a conversion price equal to $4.00. The Secured Convertible Debentures are secured by all of the assets of the Company. The Company has the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, the Company is required to issue to the holders an aggregate of 50,000 shares of common stock of the Company.

Each of the SEDA, Security Purchase Agreement and related agreements are in escrow pending our filing of this Form 10K and issuance of shares of common stock required to be issued under the agreement.

OraDisc(TM) A was approved by the FDA in September 2004.

This successful development is an important technology milestone that supports the development of the OraDisc(TM) range of products. To achieve OraDisc(TM) A approval, in addition to performing the necessary clinical studies to prove efficacy, we conducted an irritation study, a 28-day safety study and drug distribution studies. Additionally, we demonstrated safety in patients down to 12 years of age. Patients in the 700 patient clinical study and 28-day safety study completed a survey that produced very positive results with regard to perceived effectiveness, ease of application, ability of the disc to remain in place and purchase intent. These data give strong support to our overall development program. The survey data confirms market research studies that indicate a strong patient acceptance of this delivery device.

Now that OraDisc(TM) A is approved as a prescription product, we intend to move this product to market as rapidly as possible. Initially, we plan either alone

or with a marketing partner to embark on a dental campaign to gain professional endorsement for this product. Ultimately, it is our objective to move this product from prescription status to an over-the-counter consumer product. To accomplish these commercialization objectives, we intend to out license OraDisc(TM) A. In addition to royalty payments, we believe that a licensing agreement could include an upfront licensing payment and future significant payments on the achievement of milestones.

It is also our objective to gain regulatory approval for OraDisc(TM) A in all the major global markets. In Western Europe the OraDisc(TM) A product has been licensed and we are in the process of extending our licensing coverage to cover all major global markets.

On February 24, 2004 we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of $5.40. We received gross proceeds of $9,663,000 from this offering and had expenses of $647,000. The investors also received 5 year warrants to purchase 447,344 shares of our common stock at an exercise price of $7.10 per share and the placement agents received warrants in the offering to purchase 156,481 shares of our common stock at an exercise price of $5.40 per share.

On January 8, 2004 we announced that we had signed a licensing agreement with Wyeth Consumer Healthcare, a division of Wyeth, granting Wyeth the North American rights to develop and market an over-the-counter (OTC) product utilizing our OraDisc(TM) technology pending any required regulatory approvals. This agreement grants an exclusive license to market the OraDisc(TM) product in the United States, Canada and Mexico, with additional rights to extend the marketing rights worldwide.

We were incorporated in Wyoming in 1974 as Chemex Corporation, and in 1983 we changed our name to Chemex Pharmaceuticals, Inc. We changed our state of incorporation from Wyoming to Delaware on June 30, 1989. In 1996 we merged with Access Pharmaceuticals, Inc., a private Texas corporation, and changed our name to Access Pharmaceuticals, Inc. Our principal executive office is located at 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207; our telephone number is (214) 905-5100.

PRODUCTS

We have used our drug delivery technology platforms to develop the following products and product candidates:

MARKETED PRODUCTS

APHTHASOL(R) AND APTHEAL(R) (AMLEXANOX 5% PASTE)

Amlexanox 5% paste is the first drug approved by the FDA for the treatment of canker sores. Independent market research indicates that more than 8 million patients visit dentists per year in the United States with complaints of canker sores. Current estimates indicate that approximately 20% of the U.S. adult population suffers from canker sores.

We completed a Phase IV study in Ireland in November 2000 to determine if the application of amlexanox 5% paste at the first sign or symptom of canker sores can abort ulcer formation or further accelerate healing. The results confirmed that amlexanox 5% paste was effective in preventing the formation of an ulcer when used at the first sign or symptom of the disease. If this label extension is approved by regulatory authorities it could provide a major marketing opportunity to expand use of the product and to attract sufferers of canker sores to contact medical practitioners to request the product.

On July 22, 2002, we acquired from GlaxoSmithKline the patents, trademarks and technology covering the use of amlexanox for the treatment of mucosal and skin disorders. The two major components of the acquisition are the US marketing rights to amlexanox 5% paste, which is currently marketed for the treatment of canker sores under the trademark Aphthasol(R), and the remaining worldwide marketing rights for this indication which were the subject of a prior licensing agreement between the companies.

Our amlexanox 5% paste is marketed in the US as Aphthasol(R). Block Drug Company had manufactured the 5% amlexanox paste since the product was approved by the FDA in 1996 in a FDA-approved Puerto Rico facility. At such time when we acquired the US rights to Aphthasol(R), we entered into a Supply Agreement

whereby Block Drug Company was to produce Aphthasol(R) for us for a defined period of time at its Puerto Rico facility. We were subsequently advised by Block Drug Company that it was unable to comply with the terms of the Supply Agreement and that it would not be able to produce Aphthasol(R) for us. Due to Block Drug Company's production failure, we had sufficient product to supply wholesalers only through June 2003. We selected Contract Pharmaceuticals Ltd. Canada as our new manufacturer of amlexanox 5% paste and full scale production was completed in September 2004. Aphthasol(R) was re-introduced in September 2004.

We licensed the exclusive United Kingdom and Ireland rights for the sale and marketing of amlexanox 5% paste for the treatment of canker sores to ProStrakan in August 1998. Under the terms of this license, ProStrakan was responsible

for and assumed all costs associated with the regulatory approval process, including product registration, for amlexanox in the United Kingdom and the European Union (EU). Additionally, ProStrakan will make milestone payments to us on achievement of performance objectives and we will receive royalties on product sales of amlexanox.

An international outlicensing program for amlexanox is ongoing. In addition to our license agreement with ProStrakan, licensing agreements have been executed with Zambon Group for France, Germany, Holland, Belgium, Luxembourg, Switzerland, Brazil, Columbia and Italy; Meda AB for Scandinavia, the Baltic states and Iceland; Laboratorios Esteve for Spain, Portugal and Greece; Mipharm S.p.A. for Italy; Paladin Labs Inc. for Canada, EpiTan, Ltd. for Australia and New Zealand, and Orient Europharma, Co., Ltd for Taiwan, Hong-Kong, Philippines, Thailand and Singapore. Contract Pharmaceuticals Ltd. Canada has also been selected as our European supplier of amlexanox 5% paste and has been approved for European supply.

ProStrakan received marketing authorization for amlexanox 5% paste in the United Kingdom in September 2001. ProStrakan's trade name for the product is Aptheal(R). Approval to market was granted in Austria, Germany, Greece, Finland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, and Sweden. Approvals were not received under the Mutual Recognition Procedure for France, Italy and Belgium. We plan to reapply for approvals in such countries.

The Therapeutic Products Programme, the Canadian equivalent of the FDA, has issued a notice of compliance permitting the sale of amlexanox 5% paste, called Apthera(R), in Canada to Paladin Labs Inc., our Canadian partner.

RESIDERM(R) A GEL - ZINDACLIN(R) (ZINC-CLINDAMYCIN)

The complexing of zinc to a drug has the effect of enhancing the penetration of the drug into the skin and the retention of the drug in the skin. This phenomenon is called the "reservoir effect," and it makes zinc potentially effective for the delivery of dermatological drugs. We have a broad patent covering the use of zinc for such purposes. This technology is called ResiDerm(R).

We have developed, in conjunction with ProStrakan, zinc clindamycin for the treatment of acne which is marketed under the trade name Zindaclin(R). Topical acne drugs constitute an approximately $750 million per year market and clindamycin is a widely prescribed drug for the treatment of acne. Clinical studies indicate that the addition of zinc results in Zindaclin(R) being as effective applied once daily as the market leading clindamycin product applied twice daily. The activity of zinc and clindamycin, the improved stability of the product and the potential for zinc to overcome certain bacterial resistance are other potential product benefits.

In February 1998, we licensed the exclusive worldwide rights for the manufacturing, sales and marketing of zinc clindamycin pursuant to a license agreement with ProStrakan. Under the terms of the license agreement, ProStrakan has agreed to fund the development costs of zinc clindamycin and any additional compounds developed utilizing our zinc patent, including product registrations. We will share equally in all milestone payments received from the sublicensing of the compound. In addition, we will receive a royalty on sales of products based on this technology.

ProStrakan currently is marketing zinc clindamycin in the United Kingdom under the trade name Zindaclin(R). The process to achieve marketing authorization for Zindaclin(R) throughout Europe now has been completed, with approvals in most

European Union countries including the new member states and several non-European countries. We anticipate that in the next twelve months approvals will be obtained in additional countries. In addition, in May 2002 ProStrakan signed a Licensing Agreement with Fujisawa GmbH, which granted a license to Fujisawa for rights to market Zindaclin(R) in continental western Europe. Additional licenses and or distribution agreements have been signed in other countries with other companies.

Milestone Payments And Royalties By Product

The following table reflects aggregate milestone payments received through December 31, 2004, aggregate possible milestone payments under agreements signed as of December 31, 2004 and royalties received through December 31, 2004.

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Product	Milestones Received through 12/31/04	Aggregate Possible Milestones	Royalties Received through 12/31/04
<S>	<C>	<C>	<C>
Aphthasol(R) and OraDisc(TM)	$ 1,376,000	$ 6,242,000	$ -
Zindaclin(R)	$ 1,426,000	$ 1,168,000	$ 139,000

</TABLE>

PRODUCTS IN DEVELOPMENT STATUS

POLYMER PLATINATE

Chemotherapy, surgery and radiation are the major components in the clinical management of cancer patients. Chemotherapy is usually the primary treatment of hematologic malignancies, which cannot be excised by surgery. Chemotherapy is increasingly used as an adjunct to radiation and surgery to improve their effectiveness and serves as the primary therapy for some solid tumors and metastases. For chemotherapeutic agents to be effective in treating cancer patients, however, the agent must reach the target cells in effective quantities with minimal toxicity in normal tissues.

The current optimal strategy for chemotherapy involves exposing patients to the most intensive cytotoxic regimens that they can tolerate and clinicians attempt to design a combination of chemotherapeutic drugs, a dosing schedule and a method of administration to increase the probability that cancerous cells will be destroyed while minimizing the harm to healthy cells. Notwithstanding clinicians' efforts, most current chemotherapeutic drugs have significant shortcomings that limit the efficacy of chemotherapy. For example, certain cancers are inherently unresponsive to chemotherapeutic agents. Alternatively, other cancers may initially respond, but subgroups of cancer cells acquire resistance to the drug during the course of therapy and the resistant cells may survive and cause a relapse. Serious toxicity, including bone marrow suppression, renal toxicity, neuropathy, or irreversible cardiotoxicity, are some of the limitations of current anti-cancer drugs that can prevent their administration in curative doses.

Currently, platinum compounds are one of the largest selling categories of chemotherapeutic agents, with annual sales in excess of $2.0 billion. As is the case with all chemotherapeutic drugs, the use of such compounds is associated with serious systemic side effects. The drug delivery goal therefore is to enhance delivery of the drug to the tumor and minimize the amount of drug affecting normal organs in the body.

POLYMER PLATINATE (AP 5346) DACH PLATINUM

The extensive experience we have gained developing AP5280 has been applied to extend our platinum developments to include the DACH form of platinum.

Oxaliplatin, another form of DACH platinum, which was initially approved in France and in Europe in 1999 for the treatment of colorectal cancer is now also being marketed in the United States and is generating worldwide sales in excess of $1.5 billion annually. Carboplatin and Cisplatin, two approved platinum chemotherapy drugs, are not indicated for the treatment of metastatic colorectal cancer. Oxaliplatin, in combination with 5-flurouracil and folinic acid is indicated for the first-line treatment of metastatic colorectal cancer in Europe and the U.S. The colorectal cancer market is a significant opportunity as there

are over 500,000 reported new cases annually in the developed world, increasing at a rate of approximately three percent per year.

Utilizing the biocompatible water-soluble polymer HPMA as a drug carrier, AP5346 links DACH platinum to the polymer in a manner which permits the selective release of platinum in tumors. The polymer capitalizes on the biological differences in the permeability of blood vessels at tumor sites versus normal tissue. In this way, tumor selective delivery and platinum release is achieved. The ability to inhibit tumor growth has been evaluated in more than ten preclinical models. Compared with the marketed product Oxaliplatin, AP5346 showed superiority in a number of these models. Preclinical studies of the delivery of platinum to tumors in an animal model have shown that, compared with oxaliplatin at equitoxic doses, AP5346 delivers in excess of 16 times more platinum to the tumor. An analysis of tumor DNA, which is the main target for anti-cancer platinum agents, has shown that AP5346 delivers approximately 14 times more platinum to tumor DNA. Results from preclinical efficacy studies conducted in the B16 and other tumor models have also shown that AP5346 is superior to oxaliplatin in inhibiting the growth of tumors. An extensive preclinical package has been developed supporting the development of AP5346.

In the first quarter of 2005 we completed a Phase I clinical study in a multi-center study conducted in Europe, enrolled approximately 26 patients. The reporting of this study is expected to be completed in the second quarter of 2005. The European trial was designed to identify the maximum tolerated dose, dose limiting toxicities, the pharmacokinetics of the platinum in plasma and the possible antitumor activity of AP5346. The open-label, non-randomized, dose-escalation Phase I study was performed at two European centers. AP5346 was administered as an intravenous infusion over one hour, once a week on days 1, 8 and 15 of each 28-day cycle to patients with solid progressive tumors. We have obtained preliminary reports on results in 26 patients with a broad cross-section of tumor types, with doses ranging from 80-1,280 mg Pt/m2.

Of the 26 patients, 10 were not evaluable for tumor response, principally due to withdrawal from the study prior to completing the required cycle. Of the 16 evaluable patients, 2 demonstrated a partial response and 4 experienced stable disease. One of the patients who attained a partial response had a melanoma with lung metastasis; a CT scan revealed a tumor decrease of greater than 50%. The other patient who responded had ovarian cancer; she had a reduction in lymph node metastasis and remission of a liver metastasis. Also of note, a patient with cisplatin resistant cervical cancer showed a short lasting significant reduction in lung metastasis after 3 doses. However, due to toxicity, the patient could not be retreated to determine whether the partial response could be maintained.

We received clearance in January 2005 from the US Food and Drug Administration for our Investigational New Drug Application (IND) for AP5346 allowing the Company to proceed with a Phase I clinical trial for this drug candidate. We plan to initiate a study of AP5346 in combination with fluorouracil and leucovorin to evaluate drug safety and to establish a starting dose for future Phase II studies utilizing this combination. Upon the successful completion of this Phase I study, we plan to initiate a Phase II study to determine the efficacy of AP5346 in combination with fluorouracil and leucovorin in colorectal cancer patients compared with the oxaliplatin/fluorouracil/leucovorin combination, which is used extensively to treat colorectal cancer.

Due to the superior pre-clinical and clinical results achieved relative to AP5280, AP5346 is now our lead clinical candidate. Additionally, since oxaliplatin has now been shown to have activity in solid tumors, in addition to colorectal cancer, we believe that the opportunity for AP5346 has been further expanded. Consequently, further development of AP5280 has been deferred pending the clinical results achieved with AP5346.

ORADISC(TM)

Treatment of oral conditions generally relies upon the use of medications formulated as gels and pastes, that are applied to lesions in the mouth. The duration of effectiveness of these medications is typically short because the applied dose is worn away through the mechanical actions of speaking, eating, and tongue movement, and is washed away by saliva flow. To address these problems, Access developed a novel, cost-effective, commercially-viable, mucoadhesive film product that is bioerodible. This technology, known as OraDisc(TM), comprises a multi-layered film having an adhesive layer, a pre-formed film layer, and a coated backing layer. Depending upon the intended

application, a pharmaceutically active compound can be formulated within any of these layers, providing for a wide range of potential applications. The disc is simply applied by pressing it against the inner surface of the mouth. The disc stays in place, eroding over a period of time, so that subsequent removal is unnecessary. The disc delivers the drug over a period of time controlled by the rate of erosion of the disc, which is in turn controlled by the formulation of the backing layer.

OraDisc(TM) A was initially developed as a drug delivery system to treat canker sores with the same active ingredient (amlexanox) that is used in Aphthasol(R). We anticipate that higher amlexanox concentrations will be achieved at the disease site, increasing the effectiveness of the product, called OraDisc(TM) A.

OraDisc(TM) A was approved by the FDA in September 2004.

This successful development is an important technology milestone which supports the development of the OraDisc(TM) range of products. To achieve OraDisc(TM) A approval, in addition to performing the necessary clinical studies to prove efficacy, we conducted an irritation study, a 28-day safety study and drug distribution studies. Additionally, we demonstrated safety in patients down to 12 years of age. Patients in the 700 patient clinical study and 28-day safety study completed a survey which produced very positive results with regard to perceived effectiveness, ease of application, ability of the disc to remain in place and purchase intent. These data give strong support to our overall development

program. The survey data confirms market research studies which indicate a strong patient acceptance of this delivery device.

Now that OraDisc(TM) A is approved as a prescription product, we intend to move this product to market as rapidly as possible. Initially, we plan to embark on a dental campaign to gain professional endorsement for this product. Ultimately, it is our objective to move this product from prescription status to an over-the-counter consumer product. To accomplish these commercialization objectives, we intend to out license OraDisc(TM) A. In addition to royalty payments, we believe that a licensing agreement could include an upfront licensing payment and future significant payments on the achievement of milestones.

It is also our objective to gain regulatory approval for OraDisc(TM) A in all the major global markets. In Western Europe the OraDisc(TM) A product has been licensed and we are in the process of extending our licensing coverage to cover all major global markets.

We have continued to develop the OraDisc(TM) technology, and we have generated or are exploring additional prototype drug delivery products, including those for pain palliation in the oral cavity, gingivitis, cough and cold treatment, breath freshener, tooth whitening and other dental applications. In January 2004, we announced the signing of an agreement with Wyeth Consumer Healthcare for the development of an OTC product based upon the OraDisc(TM) technology.

MUCOADHESIVE LIQUID TECHNOLOGY (MLT)

Mucositis is a debilitating condition involving extensive inflammation of mouth tissue that affects an estimated 550,000 cancer patients in the United States undergoing chemotherapy and radiation treatment. Any treatment that would accelerate healing and/or diminish the rate of appearance would have a significant beneficial impact on the quality of life of these patients and may allow for more aggressive chemotherapy.

We filed an IND with the FDA in December 1999 and developed a Phase II protocol to investigate a mouthwash formulation for the prevention and treatment of mucositis in head and neck cancer patients treated with radiation with or without chemotherapy. Over 90% of head and neck cancer patients treated with radiation and chemotherapy experience mucositis. This study commenced in the first quarter of 2000. We enrolled 58 patients in the initial study which was performed at multiple sites throughout the United States.

In July 2001, we announced results from our Phase II randomized clinical study of the prevention and treatment of mucositis. The data developed confirmed that our mucoadhesive liquid technology (MLT) could represent an important advancement in the management and prevention of mucositis.

The data were retrospectively compared with two historical patient databases to evaluate the potential advantages that this technology may represent in the prevention, treatment and management of mucositis. The patient evaluation was conducted using the oral mucositis assessment scale, which qualifies the disease severity on a scale of 0-5. Key highlights of the comparison with the historical patient databases are as follows:

- the average severity of the disease was reduced by approximately 40%;
- the maximum intensity of the mucositis was approximately 35% lower; and
- the median peak intensity was approximately 50% lower.

Given the results achieved with our MLT, and the fact that in the study an amlexanox rinse showed no additional benefit, we do not plan to conduct additional clinical studies evaluating amlexanox as a preventative product candidate for mucositis. Following the completion of the Phase II study we conducted additional formulation development work to optimize the MLT technology prior to advancing clinical development. The topical application of the MLT was tested for its ability to attenuate the course of radiation-induced oral mucositis in an established hamster model. The study results clearly indicate the ability to prevent the onset of ulcerative mucositis, or delay the onset and reduce the severity of mucositis. Further clinical development of this program has been placed on hold to focus our resources on our high potential cancer therapeutics. Further development will be dependent on securing a strategic partner.

DRUG DEVELOPMENT STRATEGY

A part of our integrated drug development strategy is to form creative alliances with centers of excellence in order to obtain alternative lead compounds while minimizing the overall cost of research. We have signed agreements with ProStrakan for the delivery of topical therapeutic agents which exploit our zinc patent. Additionally, certain of our polymer platinate technology have resulted in part from a research collaboration with The School of Pharmacy, University of London.

Our strategy is to initially focus on utilizing our technology in combination with approved drug substances to develop novel patentable formulations of existing therapeutic and diagnostic products. We believe that this will expedite product development, both preclinical and clinical, and ultimately product approval. To reduce financial risk and equity financing requirements, we are directing our resources to the preclinical and early clinical phases of development. Where the size of the necessary clinical studies and cost associated with the later clinical development phases are significant, we plan to outlicense to, or co-develop with, marketing partners our current product candidates.

We will continue to expand our internal core capabilities of chemistry, formulation, analytical methods development, clinical development, biology and project management to maximize product opportunities in a timely manner. We will, however, contract the manufacturing scaleup, certain preclinical testing and product production to research organizations, contract manufacturers and strategic partners. There will be some instances where there may be significant cost savings for us to do some manufacturing scaleup (such as with our OraDisc(TM) program) and preclinical testing. We will evaluate those instances and may do the work ourselves in order to achieve cost savings. Given the current cost containment and managed care environment both in the United States and overseas and the difficulty for a small company to effectively market its products, we do not currently plan to become a fully integrated pharmaceutical company.

Consequently, we expect to form strategic alliances for product development and to outlicense the commercial rights to development partners. By forming strategic alliances with major pharmaceutical and diagnostic companies, we believe that our technology can be more rapidly developed and successfully introduced into the marketplace.

SCIENTIFIC BACKGROUND

The ultimate criteria for effective drug delivery is to control and optimize the localized release of the drug at the target site and rapidly clear the

non-targeted fraction. Conventional drug delivery systems such as controlled release, sustained release, transdermal systems and others are designed for delivering active product into the systemic circulation over time with the objective of improving patient compliance. These systems do not address the biologically relevant issues such as site targeting, localized release and clearance of drug. The major factors that impact the achievement of this ultimate drug delivery goal are the physical characteristics of the drug and the biological characteristics of the disease target sites. The physical characteristics of the drug affect solubility in biological systems, its biodistribution throughout the body, and its interactions with the intended pharmacological target sites and undesired areas of toxicity. The biological characteristics of the diseased area impact the ability of the drug to selectively interact with the intended target site to allow the drug to express the desired pharmacological activity.

We believe that our drug delivery technology platforms are differentiated from conventional drug delivery systems in that they seek to apply a disease-specific approach to improve the drug delivery process with formulations to significantly enhance the therapeutic efficacy and reduce toxicity of a broad spectrum of products.

CORE DRUG DELIVERY TECHNOLOGY PLATFORMS

Our current drug delivery technology platforms for use in cancer chemotherapy, dermatology and oral disease are:

- Synthetic Polymer Targeted Drug Delivery Technology;
- Vitamin Mediated Targeted Delivery Technology;
- Vitamin Mediated Oral Delivery Technology;

- Bioerodible Cross-Linker Technology;
- Mucoadhesive Disc Technology;
- Hydrogel Particle Aggregate Technology; and
- Residerm(R) Topical Delivery Technology.

Each of these platforms is discussed below:

SYNTHETIC POLYMER TARGETED DRUG DELIVERY TECHNOLOGY

In collaboration with The School of Pharmacy, University of London, we have developed a synthetic polymer technology, which utilizes hydroxypropylmethacrylamide with platinum, designed to exploit enhanced permeability and retention, or EPR, at tumor sites to selectively accumulate drug and control drug release. Many solid tumors possess vasculature that is hyperpermeable, or leaky, to macromolecules. In addition to this enhanced permeability, tumors usually lack effective lymphatic and/or capillary drainage. Consequently, tumors selectively accumulate circulating macromolecules, including, for example, up to 10% of an intravenous dose in mice. This effect has been termed EPR, and is thought to constitute the mechanism of action of styrene-maleic/anhydride-neocarzinostatin, or SMANCS, which is in regular clinical use in Japan for the treatment of hepatoma. These polymers take advantage of endothelial permeability as the drug carrying polymers are trapped in tumors and then taken up by tumor cells. Linkages between the polymer and drug can be designed to be cleaved extracellularly or intracellularly. The drug is released inside the tumor mass while polymer/drug not delivered to tumors is renally cleared from the body. Data generated in animal studies have shown that the polymer/drug complexes are far less toxic than free drug alone and that greater efficacy can be achieved. Thus, these polymer complexes have demonstrated significant improvement in the therapeutic index of anti-cancer drugs, including, for example, platinum.

VITAMIN MEDIATED TARGETED DELIVERY TECHNOLOGY

Most drugs are effective only when they reach a certain minimum concentration in the region of disease, yet are well distributed throughout the body contributing to undesirable side effects. It is therefore advantageous to alter the natural biodistribution of a drug to have it more localized where it is needed. Our vitamin mediated targeted delivery technology utilizes the fact that in many

diseases where there is rapid growth and/or cell division, the demand for certain vitamins increases. By coupling the drug to an appropriate vitamin, the vitamin serves as a carrier to increase the amount of drug at the disease site relative to its normal distribution.

One application of this technology is in tumor targeting. The use of cytotoxic drugs is one of the most common methods for treating a variety of malignancies including solid and non-solid tumors. The drawbacks of chemotherapeutic treatments, which include tumor resistance, cancer relapse and toxicity from severe damage to healthy tissues, has fuelled a scientific quest for novel treatments that are specifically targeted to malignant cells thus reducing damage to collateral tissues.

The design of targeted therapies involves exploitation of the difference between the structure and function of normal cells compared with malignant cells. Differences include the increased levels of surface molecules on cancer cells, which makes them more sensitive to treatment regimes that target surface molecules and differences in blood supply within and around tumor cells compared with normal cells.

Two basic types of targeting approaches are utilized, passive tumor targeting and active tumor targeting.

- passive tumor targeting involves transporting anti-cancer agents through the bloodstream to tumor cells using a "carrier" molecule. Many different carrier molecules, which can take a variety of forms (micelles, nanoparticles, liposomes and polymers), are being investigated as each provides advantages such as specificity and protection of the anti-cancer drug from degradation due to their structure, size (molecular weights) and particular interactions with tumor cells. Our polymer platinate program is a passive tumor targeting technology.

- active tumor targeting involves attaching an additional fragment to the anticancer drug and the carrier molecule to create a new "targeted" agent that will actively seek a complementary surface molecule to which it binds (preferentially located on the exterior of the tumor cells). The theory is that the targeting of the anti-cancer agent through active means to the affected cells should allow more of the anti-cancer drug to enter the tumor cell, thus amplifying the response to the treatment and reducing the toxic effect on bystander, normal tissue.

Examples of active targeting fragments include antibodies, growth factors and vitamins. Our scientists have specifically focused on using vitamin B12 and folate to more effectively target anti-cancer drugs to solid tumors.

It has been known for some time that vitamin B12 and folic acid are essential for tumor growth and as a result, receptors for these vitamins are up-regulated in certain tumors. Vitamin B12 receptor over-expression occurs in breast, lung, leukemic cells, lymphoma cells, bone, thyroid, colon, prostate and brain cancers and some other tumor lines, while folate receptor over-expression occurs in breast, lung, ovarian, endometrial, renal, colon, brain and cancers of myeloid hemotopoietic cells and methotrexate-sensitive tumors.

VITAMIN MEDIATED ORAL DELIVERY TECHNOLOGY

Oral delivery is the preferred method of administration of drugs where either long-term or daily use (or both) is required. However many therapeutics, including peptide and protein drugs, are poorly absorbed when given orally. With more and more peptide and protein based biopharmaceuticals entering the market, there is an increasing need to develop an effective oral delivery system for them, as well as for long-standing injected drugs such as insulin.

The difficulty in administering proteins orally is their susceptibility to degradation by digestive enzymes, their inability to cross the intestinal wall and their rapid excretion by the body. Over the years, many different methodologies for making protein drugs available orally have been attempted. Most of the oral protein delivery technologies involve protecting the protein degradation in the intestine. More recently, strategies have been developed that involve attaching the protein or peptide to a molecule that transports the protein across the gut wall. However, the field of oral drug delivery of proteins and peptides has yet to achieve successful commercialization of a product (although positive results have been achieved in early clinical trials for some products under development).

Many pharmaceutically active compounds such as proteins, peptides and cytotoxic agents cannot be administered orally due to their instability in the gastrointestinal tract or their inability to be absorbed and transferred to the bloodstream. A technology that would allow many of these actives to be taken orally would greatly enhance their acceptance and value. Several technologies for the protection of sensitive actives in the gastro-intestinal tract and/or enhancement of gastro-intestinal absorption have been explored and many have failed.

Our proprietary technology for oral drug delivery utilizes the body's natural vitamin B12 (VB12) transport system in the gut. The absorption of VB12 in the intestine occurs by way of a receptor-mediated endocytosis. Initially, VB12 binds to intrinsic factor (IF) in the small intestine, and the VB12-IF complex then binds to the IF receptor on the surface of the intestine. Receptor-mediated endocytosis then allows the transport of VB12 across the gut wall. After binding to another VB12-binding protein, transcobalamin II (TcII), VB12 is transferred to the bloodstream.

Our scientists discovered that VB12 will still be transported by this process even when drugs, macromolecules, or nanoparticles are coupled to VB12. Thus VB12 serves as a carrier to transfer these materials from the intestinal lumen to the bloodstream. For drugs and macromolecules that are stable in the gastro-intestinal tract, the drug or macromolecule can be coupled directly (or via a linker) to VB12. If the capacity of the VB12 transport system is inadequate to provide an effective blood concentration of the active, transport can be amplified by attaching many molecules of the drug to a polymer, to that VB12 is also attached. A further option, especially for drugs and macromolecules that are unstable in the intestine, is to formulate the drug in a nanoparticle which is then coated with VB12. Once in the bloodstream, the active is released by diffusion and/or erosion of the nanoparticle. Utilization of nanoparticles also serves to `amplify' delivery by transporting many molecules at one time due to the inherently large surface area.

Our proprietary position in this technology involves the conjugation of vitamin B12 and/or folic acid (or their analogs) to a polymer to which is also attached the drug to be delivered, or attached to a nanoparticle in which the

drug is incorporated. Since many molecules of the drug are attached to a single polymer strand, or are incorporated in a single nanoparticle, disease targeting is amplified compared to simpler conjugates involving one molecule of the vitamin with one drug molecule. However, in situations when such a simple conjugate might be preferred, our patents also encompass these VB12-drug conjugates.

BIOERODIBLE CROSS-LINKER DELIVERY TECHNOLOGY

Our scientists have developed a novel series of bioerodible cross-linkers that have the potential to be utilized with hydrogels in a number of drug delivery applications as well as several non-pharmaceutical applications. Hydrogels are very large molecules with complex three-dimensional structures capable of storing either small molecule drugs or much larger peptide and protein therapeutics. These molecules are stored within the matrix of the hydrogel. Most hydrogels are not bioerodible, therefore they deliver their payload of drug by diffusion of these molecules through the interconnecting chambers of the hydrogel. Once all of the drug has been delivered, non-bioerodible hydrogels remain in the body (unless surgically removed) as they cannot be broken down and eliminated. By comparison, our hydrogels possess bioerodible linking groups with well-defined rates of degradation in biological systems, and so release their payload of drugs by both diffusion and erosion of the hydrogel matrix. By selecting linkers with appropriate degradation rates, much greater control of drug release rates can be achieved. Once the drug has been released, erosion of the hydrogel continues until no solid hydrogel remains, eliminating the need to use an additional procedure to remove the drug delivery device. The hydrogel erodes to form much smaller water-soluble fractions which are readily eliminated from the body.

A number of possible drug delivery systems may be able to be developed using the Access bioerodible cross-linker technology, ranging from nanoparticles for intravenous administration, to larger devices which may be implanted, wound packaging materials, medicated and non-medicated for decubitus and vascular ulcers, medicated films and gels for topical applications, burn dressing and dressing for skin donor sites.

MUCOADHESIVE DISC TECHNOLOGY

Treatment of oral conditions generally relies upon the use of medications formulated as gels and pastes, which are applied to lesions in the mouth. The duration of effectiveness of these medications is typically short because the applied dose is worn away through the mechanical actions of speaking, eating, and tongue movement, and is washed away by saliva flow. To address these problems, Access developed a mucoadhesive film product that we believe is novel, cost-effective, commercially-viable and is bioerodible. This technology, known as OraDisc(TM), comprises a multi-layered film having an adhesive layer, a pre-formed film layer, and a coated backing layer. Depending upon the intended application, a pharmaceutically active compound can be formulated within any of these layers, providing for a wide range of potential applications. The disc is simply applied by pressing it against the inner surface of the mouth. The disc stays in place, eroding over a period of time, so that subsequent removal is unnecessary. The disc delivers the drug over a period of time controlled by the rate of erosion of the disc, which is in turn controlled by the formulation of the backing layer.

OraDisc(TM) was initially developed as a drug delivery system to treat canker sores with the same active ingredient (amlexanox) that is used in Aphthasol(R). We anticipate that higher amlexanox concentrations will be achieved at the disease site, increasing the effectiveness of the product, called OraDisc(TM) A.

We have continued to develop the OraDisc(TM) technology, and we have generated or are exploring additional prototype drug delivery products, including those for pain palliation in the oral cavity, gingivitis, cough and cold treatment, breath freshener, tooth whitening and other dental applications.

HYDROGEL PARTICLE AGGREGATE TECHNOLOGY

Our hydrogel particle aggregate technology provides unique materials with a broad range of properties and potential applications. While a conventional bulk hydrogel is an "infinite" network of loosely cross-linked hydrophilic polymers that swells when placed in polar solvents, we have discovered that a variety of unique biomaterials can be formed through the aggregation of hydrogel nano or micro-particles. This concept takes advantage of the inherent biocompatibility of hydrogels while overcoming problems with local stress and strain, which cause bulk hydrogels to shear. Unlike bulk hydrogels, these hydrogel particle aggregates are shape retentive, can be extruded or molded and offer properties suitable for use in a variety of in vivo medical devices,

and in novel drug delivery systems, by providing tailored regions of drug incorporation and release. The polymers used in the hydrogel particle aggregate technology have been extensively researched by the academic and scientific community and commercialized into several major medical products. They are generally accepted as safe, non-toxic and biocompatible.

This technology utilizes the inherent physical attractive forces between nanoparticles themselves and between nanoparticles and a polar solvent such as water. These particles form bulk materials that can have the same size as infinite bulk networks but allow chemical variability and much greater resistance to permanent mechanical deformation. The aggregate demonstrates many physical properties identical to those of a bulk hydrogel. However, there are important differences between aggregates and bulk materials. For example, "tough" elastomeric hydrogels used in tissue engineering constructs typically fail catastrophically when placed under high strain or shear forces. As the network begins to fail under stress, the material physically breaks down. Hydrogel nanoparticle aggregates exhibit superior performance compared to bulk materials under stress as the nanoparticles can slip past each other allowing local deformation and repair.

Another major advantage of the hydrogel particle aggregate technology is the ability to tailor the degradation of hydrogel nanoparticles and hydrogel nanoparticle aggregates. Our degradable cross-linker technology can be incorporated into the hydrogel nanoparticles allowing the formation of nanoparticles containing drug with degradation and drug release at specific rates. Potentially, aggregate materials can be formulated containing mixtures of particles degrading at different rates, and/or formulations containing different drugs each released at a predefined controlled rate.

A second level of controlled degradation is provided by the ability to tailor

the rate of particle erosion from the physically coalesced aggregate. The hydrogel can be formulated such that the aggregate is extremely tough and resilient, or formulated so that it can slowly erode at controlled rates. This is achieved through simple compositional changes during nanoparticle synthesis. The spaces between nanoparticles, or holes in the lattice, can be tailored by varying the nanoparticle size. These spaces have been used to encapsulate proteins during aggregate formation. The ability to trap a wide range of bioactive compounds between these particles in the presence of water solutions offers another major advantage, since this media is less deleterious to many compounds than solvents typically used with other drug delivery materials. These aggregates can easily be designed to remain together indefinitely in vivo, or break apart at specific rates. Pharmaceutically-active compounds trapped in a non-degradable aggregate will be released from the hydrogel by diffusion, while release is controlled by both diffusion and rate of erosion in degradable aggregates.

This technology has a variety of potential applications, such as in-dwelling medicated catheters, medicated stents, artificial discs, tissue scaffold and controlled-release drug delivery systems. We continue to develop the technology and specific applications utilizing this technology, while seeking to establish collaborations and partnerships to explore other applications.

RESIDERM(R) TOPICAL DELIVERY TECHNOLOGY

We have granted a license to ProStrakan for the development of compounds that utilize our zinc technology. The use of zinc ions to formulate topical products produces a reservoir of drug in the skin to increase the effectiveness of topically applied products and to reduce toxicity. There are many localized disease conditions, which are effectively treated by topical application of suitable pharmaceutical agents. In order for such treatments to be maximally effective, it is necessary that as much of the active agent as possible be absorbed into the skin where it can make contact with the disease condition in the dermal tissue without being lost by rubbing off on clothing or evaporation. At the same time, the agent must not penetrate so effectively through the skin that it is absorbed into the systemic circulation. This latter factor is especially important in order to minimize unwanted side effects of the pharmacologically active agent. The ideal vehicle for topically applied pharmaceuticals is one that can rapidly penetrate the skin and produce a "reservoir effect" in the skin or mucous membranes. Such a reservoir effect can be produced by complexing of suitable pharmaceutical agents with zinc ions, by an as yet unknown mechanism. This "reservoir effect" is defined as an enhancement of the skin or membrane's ability to both absorb and retain pharmacological agents, that is:

- to increase skin or membrane residence time;

- to decrease drug transit time; and
- to reduce transdermal flux.

A number of compounds are known to enhance the ability of pharmacologically active agents to penetrate the skin, but have the disadvantage of allowing rapid systemic dispersion away from the site of disease. Many topical agents, such as the retinoids used in the treatment of acne, and methotrexate, used in the treatment of psoriasis, are systemically toxic. There is, therefore, a need for a method of enhancing the ability of such agents to penetrate the skin so that a lesser total dosage may be used, while at the same time their ability to move from the skin to the systemic circulation is minimized.

Research Projects, Products and Products in Development

ACCESS DRUG PORTFOLIO

<TABLE>
<CAPTION>

Compound	Originator	Licensing Partner	Indication	FDA Filing	Clinical Stage (1)
<S>	<C>	<C>	<C>	<C>	
Cancer					
Polymer Platinate (AP5346) (2)	Access - U London	-	Ovarian, Colorectal		Phase I Clinical

		cancer	Development(5)		
Topical Delivery					
Amlexanox(3)	Takeda	ProStrakan, Zambon Esteve, Meda, Mipharm, Paladin	Aphthous ulcers	NDA	Approved
OraDisc(TM) Amlexanox (3) Biodegradable Polymer Disc	Access	ProStrakan, Zambon Esteve, Meda, Mipharm, Paladin	Aphthous ulcers	NDA	Approved
Residerm(R) A Zinc Clindamycin(4)	Access	ProStrakan, Fujisawa	Acne	PLA (6)	Approved (7)
OraDisc(TM) Benzocaine	Access	-	Oral pain	OTC	N/A
Vitamin Mediated Delivery					
Oral Delivery System	Access	- (8)	Various	Research	Pre-Clinical
Vitamin Targeted Therapeutics	Access	-	Anti-tumor	Research	Pre-Clinical

(1) For more information, see "Government Regulation" for description of clinical stages.

(2) Licensed from the School of Pharmacy, The University of London. Subject to royalty and milestone payments.

(3) Acquired from GlaxoSmithKline - Block Drug Company. Amlexanox licensing agreements executed with the following parties for the prevention and treatment of aphthous ulcers:

- ProStrakan Limited for UK and Ireland manufacturing and marketing rights.

- Zambon Group for France, Germany, Holland, Belgium, Luxembourg, Switzerland, Brazil, Columbia and Italy manufacturing and marketing rights.
- Laboratories Dr. Esteve SA for Spain, Portugal and Greece manufacturing and marketing rights.
- Mipharm SpA for Italy manufacturing and marketing rights.
- Meda, AB for Scandinavia, the Baltic states and Iceland marketing rights.
- Paladin Labs Inc. for Canada manufacturing and marketing rights.
- EpiTan, Ltd. for Australia and New Zealand marketing rights.
- Orient Europharma. Co. Ltd. for Taiwan, Hong-Kong, Malaysia, Philippines, Thailand and Singapore marketing rights.

(4) Licensed worldwide manufacturing and marketing rights to ProStrakan who sublicensed to:

- Fujisawa GmbH for continental Europe marketing rights.
- EpiTan for Australia and New Zealand marketing rights.
- Hyundai for Korea marketing rights.
- Taro Pharmaceuticals for Israel marketing rights.
- Biosintetica for Brazil marketing rights.
- Various companies for other smaller countries for marketing rights.

(5) Clinical studies being conducted in Europe and US.

(6) United Kingdom equivalent of an NDA.

(7) Marketing approval received from the Medicines Control Agency in the U.K. and product launched in March 2002. In addition there the product has been extensively approved throughout the European Union.

(8) Research collaboration agreement with Celltech Group plc.

We begin the product development effort by screening and formulating potential product candidates, selecting an optimal active and formulation approach and developing the processes and analytical methods. Pilot stability, toxicity and efficacy testing are conducted prior to advancing the product candidate into formal preclinical development. Specialized skills are required to produce these product candidates utilizing our technology. We have a core internal development capability with significant experience in developing these formulations.

Once the product candidate has been successfully screened in pilot testing, our scientists, together with external consultants, assist in designing and performing the necessary preclinical efficacy, pharmacokinetic and toxicology studies required for IND submission. External investigators and scaleup manufacturing facilities are selected in conjunction with our consultants. The initial Phase I and Phase II studies are conducted by institutions and investigators supervised and monitored by our employees and contract research organizations. We do not plan to have an extensive clinical development organization as we plan to have the advance phases of this process conducted by a development partner. Should we conduct Phase III clinical studies we expect to engage a contract research organization to perform this work.

We contract with third party contract research organizations to complete our large clinical trials and for data management of all of our clinical trials. Generally, we manage the smaller Phase I and II trials ourselves. Currently, we have one Phase I trial in process, one planned Phase I trials and two Phase II trials planned for this year.

With all of our product development candidates, we cannot assure you that the results of the in vitro or animal studies are or will be indicative of the results that will be obtained if and when these product candidates are tested in humans. We cannot assure you that any of these projects will be successfully completed or that regulatory approval of any product will be obtained.

We expended approximately $5,417,000, $6,096,000 and $7,024,000 on research and development during the years 2004, 2003 and 2002, respectively.

PATENTS

We believe that the value of technology both to us and to our potential corporate partners is established and enhanced by our broad intellectual property positions. Consequently, we have already been issued and seek to obtain additional U.S. and foreign patent protection for products under development and for new discoveries. Patent applications are filed with the U.S. Patent and Trademark Office and, when appropriate, with the Paris Convention's Patent Cooperation Treaty (PCT) Countries (most major countries in Western Europe and the Far East) for our inventions and prospective products.

Two U.S. patents and one European patent have issued and one U.S. patent and two European patent applications are pending for polymer platinum compounds. The two patents and patent applications are the result in part of our collaboration with The School of Pharmacy, University of London, from which the technology has been licensed and include a synthetic polymer, hydroxypropylmethacrylamide incorporating platinates, that can be used to exploit enhanced permeability and retention in tumors and control drug release. The patents and patent applications include a pharmaceutical composition for use in tumor treatment comprising a polymer-platinum compound through linkages that are designed to be cleaved under selected conditions to yield a platinum which is selectively released at a tumor site. The patents and patent applications also include methods for improving the pharmaceutical properties of platinum compounds.

One U.S. and two European patents have issued and one European patent is pending for the use of zinc as a pharmaceutical vehicle for enhancing the penetration and retention of drug in the skin. The patents and patent application cover the method of inducing a reservoir effect in skin and mucous membranes to enhance penetration and retention of topically applied therapeutic and cosmetic

pharmacologically active agents. The patents and patent application also relate to topical treatment methods including such reservoir effect enhancers and to pharmaceutical compositions containing them.

We have one U.S. patent and one European patent is pending for our bioerodible cross-linker technology. A number of possible drug delivery systems can be developed using the Access bioerodible cross-linker technology, ranging from nanoparticles for intravenous administration, to larger devices which may be implanted, wound packaging materials, medicated and non-medicated for decubitus and vascular ulcers, medicated films and gels for topical applications, burn dressing and dressing for skin donor sites.

We have one U.S. patent and have filed one U.S. and one European patent application for our OraDisc(TM) technology. This oral delivery vehicle potentially overcomes the difficulties encountered in using conventional paste and gel formulations for conditions in the mouth. Utilizing this technology, we anticipate that higher drug concentrations will be achieved at the disease site increasing the effectiveness of the product.

We have filed two U.S. patent applications and two European patent applications for our mucoadhesive liquid technology. Our patent applications cover a range of products utilizing our mucoadhesive liquid technology for the management of the various phases of mucositis.

We have filed two U.S. patent applications and two European patent applications for our hydrogel particle aggregate technology. Our patent applications have a variety of potential applications, such as in-dwelling medicated catheters, medicated stents, artificial discs, tissue scaffold and controlled-release drug delivery systems.

Through our Access Pharmaceuticals Australia Pty. Limited subsidiary we have three patented targeted therapeutic technologies:

- - folate conjugates of polymer therapeutics, to enhance tumor delivery by targeting folate receptors, which are upregulated in certain tumor types with two U.S. and two European patent applications;

- - the use of vitamin B12 to target the transcobalamin II receptor which is upregulated in numerous diseases including cancer, rheumatoid arthritis, certain neurological and autoimmune disorders with two U.S. patents and three U.S. and four European patent applications; and

- - oral delivery of a wide variety of molecules which cannot otherwise be orally administered, utilizing the active transport mechanism which transports vitamin B12 into the systemic circulation with six U.S. patents and two European patents and one U.S. and one European patent application.

We also have a patent for amlexanox and the worldwide rights, excluding Japan, for the use of amlexanox for oral and dermatological use.

We have a strategy of maintaining an ongoing line of patent continuation applications for each major category of patentable carrier and delivery technology. By this approach, we are extending the intellectual property protection of our basic targeting technology and initial agents to cover additional specific carriers and agents, some of which are anticipated to carry the priority dates of the original applications.

GOVERNMENT REGULATION

We are subject to extensive regulation by the federal government, principally by the FDA, and, to a lesser extent, by other federal and state agencies as well as comparable agencies in foreign countries where registration of products will be pursued. Although a number of our formulations incorporate extensively tested drug substances, because the resulting formulations make claims of enhanced efficacy and/or improved side effect profiles, they are expected to be classified as new drugs by the FDA.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern the testing, manufacturing, safety, labeling, storage, shipping and record keeping of our products. The FDA has the authority to approve or not approve new drug applications and inspect research, clinical and manufacturing records and facilities.

Among the requirements for drug approval and testing is that the prospective manufacturer's facilities and methods conform to the FDA's Code of Good Manufacturing Practices regulations, which establish the minimum requirements for methods to be used in, and the facilities or controls to be used during, the production process. Such facilities are subject to ongoing FDA inspection to insure compliance.

The steps required before a pharmaceutical product may be produced and marketed in the U.S. include preclinical tests, the filing of an IND with the FDA, which must become effective pursuant to FDA regulations before human clinical trials may commence, numerous phases of clinical testing and the FDA approval of a NDA prior to commercial sale.

Preclinical tests are conducted in the laboratory, usually involving animals, to evaluate the safety and efficacy of the potential product. The results of preclinical tests are submitted as part of the IND application and are fully reviewed by the FDA prior to granting the sponsor permission to commence clinical trials in humans. All trials are conducted under International Conference on Harmonization, or ICH, good clinical practice guidelines. All investigator sites and sponsor facilities are subject to FDA inspection to insure compliance. Clinical trials typically involve a three-phase process. Phase I, the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages and in some indications such as cancer and HIV, as preliminary evidence of efficacy in humans. Phase II involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. When a product is found safe, an initial efficacy is established in Phase II, it is then evaluated in Phase III clinical trials. Phase III trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit to risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA for approval to commence commercial sales.

The process of forming the requisite testing, data collection, analysis and compilation of an IND and an NDA is labor intensive and costly and may take a protracted time period. In some cases, tests may have to be redone or new tests instituted to comply with FDA requests. Review by the FDA may also take considerable time and there is no guarantee that an NDA will be approved. Therefore, we cannot estimate with any certainty the length of the approval cycle.

We are also governed by other federal, state and local laws of general applicability, such as laws regulating working conditions, employment practices, as well as environmental protection.

COMPETITION

The pharmaceutical and biotechnology industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and other product areas where we may develop and market products in the future. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technical resources than are available to us. Additionally, many of our potential competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our product lines. Our potential products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be addressed by our developments, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our potential competitors. Our business, financial condition and results of operation could be materially adversely affected by any one or more of such developments. We cannot assure you that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or with the assistance of major health care companies in areas where we are developing product candidates. We are aware of certain development projects for products to treat or prevent certain diseases targeted by us, the existence of these potential products or other products or treatments of which we are not aware, or products or

treatments that may be developed in the future, may adversely affect the marketability of products developed by us.

The principal competitors in the polymer area are Cell Therapeutics, Daiichi, Enzon and Inhale which are developing alternate drugs in combination with polymers. We believe we are the only company conducting clinical studies in the polymer drug delivery of platinum compounds. We believe that the principal current competitors to our polymer targeting technology fall into two categories: monoclonal antibodies and liposomes. We believe that our technology potentially represents a significant advance over these older technologies because our technology provides a system with a favorable pharmacokinetic profile.

A number of companies are developing or may in the future engage in the development of products competitive with the Access polymer delivery system. Several companies are working on targeted monoclonal antibody therapy including Bristol-Myers Squibb, Centocor (acquired by Johnson & Johnson), GlaxoSmithKline, Imclone and Xoma. Currently, liposomal formulations being developed by Gilead Sciences and Alza Corporation (acquired by Johnson & Johnson), are the major competing intravenous drug delivery formulations that deliver similar drug substances.

Products developed from our Residerm(R) technology will compete for a share of the existing market with numerous products which have become standard treatments recommended or prescribed by dermatologists. Zindaclin(R), which is the first product developed utilizing our Residerm(R) technology, will compete with products including Benzamycin, marketed by a subsidiary of Aventis; Cleocin-T and a generic topical clindamycin, marketed by Pharmacia; Benzac, marketed by a subsidiary of L'Oreal; and Triaz, marketed by Medicis Pharmaceutical Corp.

Aphthasol(R) is the only clinically proven product to accelerate the healing of canker sores. There are numerous products, including prescription steroids such as Kenalog in OraBase, and many over-the-counter pain relief formulations that incorporate a local anesthetic used for the treatment of this condition.

In the area of advanced drug delivery, which is the focus of our early stage research and development activities, a number of companies are developing or evaluating enhanced drug delivery systems. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as various alternative delivery system technologies achieve similar if not identical advantages.

Even if our products are fully developed and receive required regulatory approval, of which there can be no assurance, we believe that our products can only compete successfully if marketed by a company having expertise and a strong presence in the therapeutic area. Consequently, we do not currently plan to establish an internal marketing organization. By forming strategic alliances with major and regional pharmaceutical companies,

management believes that our development risks should be minimized and that the technology potentially could be more rapidly developed and successfully introduced into the marketplace.

EMPLOYEES

As of March 15, 2005, we had 35 full time employees, 17 of whom have advanced scientific degrees. Of these employees, 31 are engaged in, or directly supporting research and development activities and four are in business administration positions. We have never experienced employment-related work stoppages and consider that we maintain good relations with our personnel. In addition, to complement our internal expertise, we have contracts with scientific consultants, contract research organizations and university research laboratories that specialize in various aspects of drug development including clinical development, regulatory affairs, toxicology, process scale-up and preclinical testing.

WEB AVAILABILITY

We make available free of charge through our web site, www.accesspharma.com, our annual reports on Form 10-K and other reports required under the Securities and Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are filed with, or furnished to, the Securities and Exchange Commission as well as certain of our corporate governance policies, including the charters

for the Board of Director's audit, compensation and nominating and corporate governance committees and our code of ethics, corporate governance guidelines and whistleblower policy. We will provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207 attn: Investor Relations.

RISK FACTORS

This Annual Report on Form 10-K contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, and that involve risks and uncertainties, including, but not limited to the uncertainties associated with research and development activities, clinical trials, our ability to raise capital, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations, future cash flow, the timing and receipt of licensing and milestone revenues, the future success of our marketed products and products in development, our ability to manufacture amlexanox products in commercial quantities, our sales projections, and the sales projections of our licensing partners, our ability to achieve licensing milestones and other risks described below as well as those discussed elsewhere in this 10-K, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission. Forward-looking statements contained in this Form 10-K include, but are not limited to anticipated product approvals and timing thereof, the terms of future licensing arrangements, our ability to secure additional financing for our operations, our net cash burn rate for the next twelve months to be approximately $600,000 per month, our outstanding convertible notes, and our expected capital expenditures.

WE HAVE EXPERIENCED A HISTORY OF LOSSES AND WE EXPECT TO INCUR FUTURE LOSSES.

We have recorded minimal revenue to date and we have incurred a cumulative operating loss of approximately $64.4 million through December 31, 2004. Losses for the years ended 2004, 2003 and 2002 were $10,238,000, $6,935,000 and $9,384,000, respectively. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop clinical drug candidates and from the associated administrative costs. We expect to incur additional operating losses over the next several years. We also expect cumulative losses to increase due to expanded research and development efforts and preclinical and clinical trials. Our net cash burn rate for the twelve months of 2004 was approximately $750,000 per month. We project our net cash burn rate for the next twelve months to be approximately $600,000 per month. Capital expenditures are forecasted to be minor for the next twelve months since most of our new equipment is leased and the lease expense is included in the calculation of the net cash burn rate.

WE DO NOT HAVE SIGNIFICANT OPERATING REVENUE AND WE MAY NEVER ATTAIN PROFITABILITY.

To date, we have funded our operations primarily through private sales of common stock and convertible notes. Contract research payments and licensing fees from corporate alliances and mergers have also provided funding for our

operations. Our ability to achieve significant revenue or profitability depends upon our ability to successfully complete the development of drug candidates, to develop and obtain patent protection and regulatory approvals for our drug candidates and to manufacture and commercialize the resulting drugs. We have not received significant royalties for sales of amlexanox, Zindaclin(R) or OraDisc(TM) products to date and we may not generate significant revenues or profits from the sale of these products in the future. Furthermore, we may not be able to ever successfully identify, develop, commercialize, patent, manufacture, obtain required regulatory approvals and market any additional products. Moreover, even if we do identify, develop, commercialize, patent, manufacture, and obtain required regulatory approvals to market additional products, we may not generate revenues or royalties from commercial sales of these products for a significant number of years, if at all. Therefore, our proposed operations are subject to all the risks inherent in the establishment of a new business enterprise. In the next few years, our revenues may be limited to minimal product sales and royalties, any amounts that we receive under strategic partnerships and research or drug development collaborations that we may establish and, as a result, we may be unable to achieve or maintain profitability in the future or to achieve significant revenues in order to fund

our operations.

A FAILURE TO OBTAIN NECESSARY ADDITIONAL CAPITAL IN THE FUTURE COULD JEOPARDIZE OUR OPERATIONS.

We have issued an aggregate of $13,530,000 of convertible notes, which are due in two parts -- $8,030,000 is due on September 13, 2005 and $5,500,000 is due on September 13, 2008. The notes may convert to common stock at a conversion price of $5.50 and we can redeem the notes for the principal amount of the notes plus interest if our common stock trades above a price of $8.25 for any period of ten consecutive trading days prior to our notice of redemption. We are also issuing $2,633,000 of Secured Convertible Notes due March 31, 2006. Such Secured Convertible Notes convert at $4.00 per share. We do not have sufficient funds to repay our convertible notes at their maturity. We may not be able to restructure the convertible notes or obtain additional financing to repay them on terms acceptable to us, if at all. If we raise additional funds by selling equity securities including in connection with our SEDA with Cornell Capital, the relative equity ownership of our existing investors would be diluted and the new investors could obtain terms more favorable than previous investors. A failure to restructure our convertible notes or obtain additional funding to repay the convertible notes and support our working capital and operating requirements, could cause us to be in default of our convertible notes and prevent us from making expenditures that are needed to allow us to maintain our operations.

OUR FINANCIAL CONDITION AND THE RESTRICTIVE COVENANTS CONTAINED IN OUR OUTSTANDING CONVERTIBLE NOTES MAY LIMIT OUR ABILITY TO BORROW ADDITIONAL FUNDS OR TO RAISE ADDITIONAL EQUITY AS MAY BE REQUIRED TO FUND OUR FUTURE OPERATIONS.

We incurred significant losses from operations of $9.1 million for the year ended December 31, 2004 and $8.2 million for the year ended December 31, 2003. Moreover, the terms of our outstanding Convertible Notes may limit our ability to, among other things:

- incur additional debt;
- pay cash dividends, redeem, retire or repurchase our stock or change our capital structure;
- enter into certain transactions with affiliates;
- create additional liens on our assets; or
- issue certain types of preferred stock or issue common stock at below market prices.

Our ability to borrow additional funds or raise additional equity may be limited by our financial condition, in addition to the terms of our outstanding debt. Additionally, events such as our inability to continue to reduce our loss from continuing operations, could adversely affect our liquidity and our ability to attract additional funding as required.

WE MAY NOT BE ABLE TO PAY OUR DEBT AND OTHER OBLIGATIONS AND OUR ASSETS MAY BE SEIZED AS A RESULT.

We may not generate the cash flow required to pay our liabilities as they become due. As of March 30, 2005, our outstanding debt included approximately $8.03 million of our Convertible Subordinated Notes due in September 2005, $5.5 million of our Convertible Subordinated Notes due in September 2008 and $2,633,000 of our Secured Convertible Notes due in March 2006.

We may be unable to repay or repurchase the secured convertible notes due in March 2006 and convertible subordinated notes due in September 2005 and September 2008 upon a repurchase event and be forced into bankruptcy.

The holders of our Convertible Notes may require us to repurchase or prepay all of the outstanding Convertible Notes under certain circumstances. We may not have sufficient cash reserves to repurchase the Convertible Notes at such time, which would cause an event of default under the Convertible Notes and may force us to declare bankruptcy.

OUR OBLIGATIONS UNDER THE SECURED DEBENTURES ARE SECURED BY ALL OF OUR ASSETS

Our obligations under the $2,633,000 Secured Debentures are secured by all of

our assets. As a result, if we default under the terms of the Secured Debentures or related agreements, including our failure to issue shares of common stock upon conversion by the holder, our failure to timely file a registration statement or have such registration statement declared effective, breach of any covenant, representation or warranty in the Securities Purchase Agreement or related Secured Debentures or the commencement of a bankruptcy, insolvency, reorganization or liquidation proceeding against the Company could require the early repayment of the convertible debentures, if the default is not cured with the specified grace period. In addition we could be required to issue and the holders would have the ability to sell up to 2,891,723 shares of our Common Stock and/or the holders could foreclose their security interest and liquidate some or all of the assets of the Company and we could cease to operate.

OUR STANDBY EQUITY DISTRIBUTION AGREEMENT MAY HAVE A DILUTIVE IMPACT ON OUR STOCKHOLDERS.

We are to a great extent dependent on external financing to fund our operations. Our financial needs may be partially provided from the SEDA. The issuance of shares of our common stock under SEDA will have a dilutive impact on our other stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. In addition, if we access the SEDA, we will issue shares of our common stock to Cornell Capital Partners at a discount of 2% of the lowest daily volume weighted average of our common stock during a specified period of trading days after we access the SEDA. Issuing shares at a discount will further dilute the interests of other stockholders.

To the extent that Cornell sells shares of our common stock issued under SEDA to third parties, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Cornell may cause holders of our common stock to sell their shares, or it may encourage short sales of our common stock or either similar transactions. This could contribute to a decline in the stock price of our common stock.

WE MAY NOT SUCCESSFULLY COMMERCIALIZE OUR DRUG CANDIDATES.

Our drug candidates are subject to the risks of failure inherent in the development of pharmaceutical products based on new technologies and our failure to develop safe, commercially viable drugs would severely limit our ability to become profitable or to achieve significant revenues. We may be unable to successfully commercialize our drug candidates because:

- some or all of our drug candidates may be found to be unsafe or ineffective or otherwise fail to meet applicable regulatory standards or receive necessary regulatory clearances;

- our drug candidates, if safe and effective, may be too difficult to develop into commercially viable drugs;

- it may be difficult to manufacture or market our drug candidates on a large scale;

- proprietary rights of third parties may preclude us from marketing our drug candidates; and

- third parties may market superior or equivalent drugs.

THE SUCCESS OF OUR RESEARCH AND DEVELOPMENT ACTIVITIES, UPON WHICH WE PRIMARILY FOCUS, IS UNCERTAIN.

Our primary focus is on our research and development activities and the commercialization of compounds covered by proprietary biopharmaceutical patents and patent applications. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual research and development costs, therefore, could exceed budgeted amounts and estimated time frames may

require extension. Cost overruns, unanticipated regulatory delays or demands, unexpected adverse side effects or insufficient therapeutic efficacy will prevent or substantially slow our research and development effort and our business could ultimately suffer. We anticipate that we will remain principally engaged in research and development activities for an indeterminate, but substantial, period of time.

WE MAY BE UNABLE TO OBTAIN NECESSARY ADDITIONAL CAPITAL TO FUND OPERATIONS IN THE FUTURE.

We require substantial capital for our development programs and operating expenses, to pursue regulatory clearances and to prosecute and defend our intellectual property rights. We believe that our existing capital resources, interest income, product sales, royalties and revenue from possible licensing agreements and collaborative agreements will be sufficient to fund our currently expected operating expenses (other than debt obligations including the $8,030,000 of convertible notes which are required to be repaid in September 2005 and $2,633,000 in March 2006) and capital requirements for twelve months. However, unless our convertible notes convert to common stock prior to their maturity or are restructured, we will need to raise substantial additional capital to support our ongoing operations and debt obligations because our convertible notes will mature and/or our actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including :

- the sales levels of our marketed products;
- the results of our research and development programs;
- the timing and results of preclinical and clinical trials;
- our ability to maintain existing and establish new collaborative agreements with other companies to provide funding to us;
- technological advances; and
- activities of competitors and other factors.

If we do raise additional funds by issuing equity securities, further dilution to existing stockholders would result and future investors may be granted rights superior to those of existing stockholders. If adequate funds are not available to us through additional equity offerings, we may be required to delay, reduce the scope of or eliminate one or more of our research and development programs or to obtain funds by entering into arrangements with collaborative partners or others that require us to issue additional equity securities or to relinquish rights to certain technologies or drug candidates that we would not otherwise issue or relinquish in order to continue independent operations.

WE MAY BE UNABLE TO SUCCESSFULLY DEVELOP, MARKET, OR COMMERCIALIZE OUR PRODUCTS OR OUR PRODUCT CANDIDATES WITHOUT ESTABLISHING NEW RELATIONSHIPS AND MAINTAINING CURRENT RELATIONSHIPS.

Our strategy for the research, development and commercialization of our potential pharmaceutical products may require us to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others, in addition to our existing relationships with other parties. Specifically, we may seek to joint venture, sublicense or enter other marketing arrangements with parties that have an established marketing capability or we may choose to pursue the commercialization of such products on our own. We may, however, be unable to establish such additional collaborative arrangements, license agreements, or marketing agreements as we may deem necessary to develop, commercialize and market our potential pharmaceutical products on acceptable terms. Furthermore, if we maintain and establish arrangements or relationships with third parties, our business may depend upon the successful performance by these third parties of their responsibilities under those arrangements and relationships. For our commercialized products we currently rely upon the following relationships in the following marketing territories for sales, manufacturing or regulatory approval efforts:

- amlexanox 5% paste
  - ProStrakan Ltd. - United Kingdom and Ireland manufacturing, marketing rights and regulatory approval
  - Zambon Group - France, Germany, Holland, Belgium, Luxembourg, Switzerland, Brazil, Colombia and Italy manufacturing and marketing rights
  - Laboratories Dr. Esteve SA - Spain, Portugal and Greece manufacturing and marketing rights

  - Meda, AB for Scandinavia, the Baltic states and Iceland marketing rights
  - Mipharm SpA for Italy manufacturing and marketing rights
  - Paladin Labs, Inc. for Canada manufacturing and marketing rights
  - EpiTan, Ltd. for Australia and New Zealand for marketing rights
  - Orient Europharma, Co., Ltd. for Taiwan, Hong-Kong, Malaysia, Philippines, Thailand and Singapore for marketing rights

- Zindaclin(R) and Residerm(R)
  - ProStrakan Ltd. - worldwide manufacturing, marketing and regulatory approval rights
  - Fujisawa GmbH - sublicensed continental Europe marketing rights
  - EpiTan, Ltd. - sublicensed Australia and New Zealand marketing rights
  - Hyundai - sublicensed Korea marketing rights
  - Taro - sublicensed Israel marketing rights
  - Biosintetica - sublicensed Brazil marketing rights
  - Six companies for eleven other smaller countries - sublicensed marketing rights

For one of our OraDisc(TM) products in development, on January 6, 2004, we entered into an exclusive license and supply agreement with Wyeth Consumer Healthcare for sales of the product in North America. If this product is marketed, we will be dependent upon Wyeth Consumer Healthcare for sales of such product in this territory.

Our ability to successfully commercialize, and market our products and product candidates could be limited if a number of these existing relationships were terminated.

Furthermore, our strategy with respect to our polymer platinate program is to enter into a licensing agreement with a pharmaceutical company pursuant to which the further costs of developing a product would be shared with our licensing partner. Although we have had discussions with potential licensing partners with respect to our polymer platinate program, to date we have not entered into any licensing arrangement. We may be unable to execute our licensing strategy for polymer platinate.

WE MAY BE UNABLE TO SUCCESSFULLY MANUFACTURE OUR PRODUCTS AND OUR PRODUCT CANDIDATES IN CLINICAL QUANTITIES OR FOR COMMERCIAL PURPOSES WITHOUT THE ASSISTANCE OF CONTRACT MANUFACTURERS, WHICH MAY BE DIFFICULT FOR US TO OBTAIN AND MAINTAIN.

We have limited experience in the manufacture of pharmaceutical products in clinical quantities or for commercial purposes and we may not be able to manufacture any new pharmaceutical products that we may develop. As a result, we have established, and in the future intend to establish arrangements with contract manufacturers to supply sufficient quantities of products to conduct clinical trials and for the manufacture, packaging, labeling and distribution of finished pharmaceutical products if any of our potential products are approved for commercialization. If we are unable to contract for a sufficient supply of our potential pharmaceutical products on acceptable terms, our preclinical and human clinical testing schedule may be delayed, resulting in the delay of our clinical programs and submission of product candidates for regulatory approval, which could cause our business to suffer. Our business could suffer if there are delays or difficulties in establishing relationships with manufacturers to produce, package, label and distribute our finished pharmaceutical or other medical products, if any, market introduction and subsequent sales of such products. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by the FDA. In this regard, the FDA will not issue a pre-market approval or product and establishment

licenses, where applicable, to a manufacturing facility for the products until the manufacturing facility passes a pre-approval plant inspection. If we are unable to obtain or retain third party manufacturing on commercially acceptable terms, we may not be able to commercialize our products as planned. Our potential dependence upon third parties for the manufacture of our products may adversely affect our ability to generate profits or acceptable profit margins and our ability to develop and deliver such products on a timely and competitive basis.

Our amlexanox 5% paste is marketed in the US as Aphthasol(R). We selected Contract Pharmaceuticals Ltd. Canada as our new manufacturer of amlexanox 5% paste and they manufactured product for the US market and initial qualifying batches of the product for Europe. We re-launched Aphthasol(R) in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004.

Amlexanox 5% paste was approved by regulatory authorities for sale in the UK. Approval to market was granted in Austria, Germany, Greece, Finland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, and Sweden. We did not receive approvals for France, Italy and Belgium. We licensed manufacturing rights to ProStrakan, Zambon, Esteve and Mipharm for specific countries in Europe. Contract Pharmaceuticals Ltd. Canada has also been selected as our European supplier of amlexanox 5% paste and this facility has been approved for European supply.

We licensed our patents for worldwide manufacturing and marketing for Zindaclin(R) and our ResiDerm(R) technology to ProStrakan Ltd. for the period of the patents. We receive a share of the licensing revenues and royalty on the sales of the product. ProStrakan has a contract manufacturer for Zindaclin(R) which is a European Union approved facility. Zindaclin(R) was approved in the UK and throughout Europe in most European Union countries including new member states and several non-European markets. Zindaclin(R) is marketed in the UK, France, Germany, Ireland, Belgium, Cyprus, Israel and Korea. Zindaclin(R) is under review in other markets including Australia, New Zealand, Brazil and others.

We received regulatory approval from the FDA to manufacture and sell OraDisc(TM) A in September 2004 and are proceeding with our manufacturing and marketing plans for 2005.

AP5346 is manufactured by third parties for our Phase I/II clinical trials. Manufacturing is ongoing for the current clinical trials. Certain manufacturing steps are conducted by the Company to enable significant cost savings to be realized.

WE ARE SUBJECT TO EXTENSIVE GOVERNMENTAL REGULATION WHICH INCREASES OUR COST OF DOING BUSINESS AND MAY AFFECT OUR ABILITY TO COMMERCIALIZE ANY NEW PRODUCTS THAT WE MAY DEVELOP.

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish their safety and efficacy. All of our drugs and drug candidates require receipt and maintenance of governmental approvals for commercialization. Preclinical and clinical trials and manufacturing of our drug candidates will be subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product. The status of our principal products is as follows:

- 5% amlexanox paste is an approved product for sale in the US (Aphthasol(R)); approved in the UK and Canada but not yet sold; approved in ten EU countries;

- Zindaclin(R) is an approved product for sale in the UK and extensively throughout European Union countries; in the approval process in other markets.

- OraDisc(TM) A is an approved product for sale in the US as of September 2004; we are completing steps for manufacturing and sale of the product in 2005.

- Our other OraDisc(TM) products are currently in the pre-clinical

phase.

- AP5346 is currently in a Phase I trial in Europe.

- AP5346 has been approved for a Phase I trial in the US by the FDA.

- Mucoadhesive liquid technology patient recruitment in the clinical trial is on hold pending commercial developments.

- Vitamin mediated delivery technology is currently in the pre-clinical phase.

- We also have other products in the preclinical phase.

Due to the time consuming and uncertain nature of the drug candidate development process and the governmental approval process described above, we cannot assure you when we, independently or with our collaborative partners, might submit a New Drug Application, or "NDA", for FDA or other regulatory review.

Government regulation also affects the manufacturing and marketing of pharmaceutical products. Government regulations may delay marketing of our potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval could adversely affect our marketing as well as our ability to generate significant revenues from commercial sales. Our drug candidates

may not receive FDA or other regulatory approvals on a timely basis or at all. Moreover, if regulatory approval of a drug candidate is granted, such approval may impose limitations on the indicated use for which such drug may be marketed. Even if we obtain initial regulatory approvals for our drug candidates, Access, our drugs and our manufacturing facilities would be subject to continual review and periodic inspection, and later discovery of previously unknown problems with a drug, manufacturer or facility may result in restrictions on the marketing or manufacture of such drug, including withdrawal of the drug from the market. The FDA and other regulatory authorities stringently apply regulatory standards and failure to comply with regulatory standards can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions and criminal prosecution.

THE UNCERTAINTY ASSOCIATED WITH PRECLINICAL AND CLINICAL TESTING MAY AFFECT OUR ABILITY TO SUCCESSFULLY COMMERCIALIZE NEW PRODUCTS.

Before we can obtain regulatory approvals for the commercial sale of any of our potential drugs, the drug candidates will be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. Preclinical or clinical trials of any of our future drug candidates may not demonstrate the safety and efficacy of such drug candidates at all or to the extent necessary to obtain regulatory approvals. In this regard, for example, adverse side effects can occur during the clinical testing of a new drug on humans which may delay ultimate FDA approval or even lead us to terminate our efforts to develop the drug for commercial use. Companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials. In particular, OraDisc(TM) and polymer platinate have taken longer to progress through clinical trials than originally planned. This extra time has not been related to concerns of the formulations but rather due to the lengthy regulatory process. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate. A delay or failure to receive regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in our attempts to further develop such candidates and obtain future regulatory approval.

WE MAY INCUR SUBSTANTIAL PRODUCT LIABILITY EXPENSES DUE TO THE USE OR MISUSE OF OUR PRODUCTS FOR WHICH WE MAY BE UNABLE TO OBTAIN INSURANCE COVERAGE.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. These risks will expand with respect to our drug candidates, if any, that receive regulatory approval for commercial sale and we may face substantial liability for damages

in the event of adverse side effects or product defects identified with any of our products that are used in clinical tests or marketed to the public. We generally procure product liability insurance for drug candidates that are undergoing human clinical trials. Product liability insurance for the biotechnology industry is generally expensive, if available at all, and as a result, we may be unable to obtain insurance coverage at acceptable costs or in a sufficient amount in the future, if at all. We may be unable to satisfy any claims for which we may be held liable as a result of the use or misuse of products which we have developed, manufactured or sold and any such product liability claim could adversely affect our business, operating results or financial condition.

WE MAY INCUR SIGNIFICANT LIABILITIES IF WE FAIL TO COMPLY WITH STRINGENT ENVIRONMENTAL REGULATIONS OR IF WE DID NOT COMPLY WITH THESE REGULATIONS IN THE PAST.

Our research and development processes involve the controlled use of hazardous materials. We are subject to a variety of federal, state and local governmental laws and regulations related to the use, manufacture, storage, handling and disposal of such material and certain waste products. Although we believe that our activities and our safety procedures for storing, using, handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such accident, we could be held liable for any damages that result and any such liability could exceed our resources.

INTENSE COMPETITION MAY LIMIT OUR ABILITY TO SUCCESSFULLY DEVELOP AND MARKET COMMERCIAL PRODUCTS.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our competitors in the United States and elsewhere are numerous and include, among others,

major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions.

The following products may compete with polymer platinate:

- - Cisplatin, marketed by Bristol-Myers-Squibb, the originator of the drug, and several generic manufacturers;

- - Carboplatin, marketed by Bristol-Myers-Squibb in the US; and

- - Oxaliplatin, marketed exclusively by Sanofi-Synthelabo.

The following companies are working on therapies and formulations that may be competitive with our polymer platinate:

- - Antigenics and Regulon are developing liposomal formulations; and

- - American Pharmaceutical Partners, Cell Therapeutics, Daiichi, Enzon and Debio are developing alternate drugs in combination with polymers and other drug delivery systems.

The following products may compete with Resiferm(R) products:

- - Benzamycin, marketed by a subsidiary of Aventis;

- - Cleocin-T and a generic topical clindamycin, marketed by Pfizer;

- - Benzac, marketed by Galderma; and

- - Triaz, marketed by Medicis Pharmaceutical Corp.

Technology and prescription steroids such as Kenalog in OraBase, developed by Bristol-Myers Squibb, may compete with our commercialized Aphthasol(R) product. OTC products including Orajel - Del Laboratories and Anbesol - Wyeth Consumer Healthcare also compete in the aphthous ulcer market.

Companies working on therapies and formulations that may be competitive with our vitamin mediated drug delivery system are Bristol-Myers-Squibb, Centocor (acquired by Johnson & Johnson), GlaxoSmithKline, Imclone and Xoma which are

developing targeted monoclonal antibody therapy.

Amgen, CuraGen, McNeil, MGI Pharma and OSI Pharmaceuticals are developing products to treat mucositis that may compete with our mucoadhesive liquid technology.

BioDelivery, Biovail Corporation, Cellgate, CIMA Labs, Inc., Depomed Inc., Emisphere Technologies, Inc., Eurand, Flamel Technologies, Nobex and Xenoport are developing products which compete with our oral drug delivery system.

Many of these competitors have and employ greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

In addition, some of our competitors have greater experience than we do in conducting preclinical and clinical trials and obtaining FDA and other regulatory approvals. Accordingly, our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than we do. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage. Drugs resulting from our research and development efforts or from our joint efforts with collaborative partners therefore may not be commercially competitive with our competitors' existing products or products under development.

OUR ABILITY TO SUCCESSFULLY DEVELOP AND COMMERCIALIZE OUR DRUG CANDIDATES WILL SUBSTANTIALLY DEPEND UPON THE AVAILABILITY OF REIMBURSEMENT FUNDS FOR THE COSTS OF THE RESULTING DRUGS AND RELATED TREATMENTS.

The successful commercialization of, and the interest of potential collaborative partners to invest in the development of our drug candidates, may depend substantially upon reimbursement of the costs of the resulting drugs and related treatments at acceptable levels from government authorities, private health insurers and other organizations, including health maintenance organizations, or HMOs. To date, the costs of our marketed products Aphthasol(R) and Zindaclin(R) generally have been reimbursed at acceptable levels; however, the amount of such reimbursement in the United States or elsewhere may be decreased in the future or may be unavailable for any drugs that we may develop in the future. Limited reimbursement for the cost of any drugs that we develop may reduce the demand for, or price of such drugs, which would hamper our ability to obtain collaborative partners to commercialize our drugs, or to obtain a sufficient financial return on our own manufacture and commercialization of any future drugs.

THE MARKET MAY NOT ACCEPT ANY PHARMACEUTICAL PRODUCTS THAT WE SUCCESSFULLY DEVELOP.

The drugs that we are attempting to develop may compete with a number of well-established drugs manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any drugs developed by us will depend on a number of factors, including the establishment and demonstration of the clinical efficacy and safety of our drug candidates, the potential advantage of our drug candidates over existing therapies and the reimbursement policies of government and third-party payers. Physicians, patients or the medical community in general may not accept or use any drugs that we may develop independently or with our collaborative partners and if they do not, our business could suffer.

In 1996, the 5% amlexanox paste product was approved for sale in the United States. To date, the product sales have not been significant. On July 22, 2002, we acquired the rights to it from Block Drug Company. The product has been approved in the UK and Canada but has not been launched in any markets other than the United States. We re-launched Aphthasol(R) in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004.

We received regulatory approval from the FDA to manufacture and sell OraDisc(TM) A in September 2004 and are proceeding with our manufacturing and marketing plans for 2005.

TRENDS TOWARD MANAGED HEALTH CARE AND DOWNWARD PRICE PRESSURES ON MEDICAL PRODUCTS AND SERVICES MAY LIMIT OUR ABILITY TO PROFITABLY SELL ANY DRUGS THAT WE

MAY DEVELOP.

Lower prices for pharmaceutical products may result from:

- third-party payers' increasing challenges to the prices charged for medical products and services;

- the trend toward managed health care in the United States and the concurrent growth of HMOs and similar organizations that can control or significantly influence the purchase of healthcare services and products; and

- legislative proposals to reform healthcare or reduce government insurance programs.

The cost containment measures that healthcare providers are instituting, including practice protocols and guidelines and clinical pathways, and the effect of any healthcare reform, could limit our ability to profitably sell any drugs that we may successfully develop. Moreover, any future legislation or regulation, if any, relating to the healthcare industry or third-party coverage and reimbursement, may cause our business to suffer.

WE MAY NOT BE SUCCESSFUL IN PROTECTING OUR INTELLECTUAL PROPERTY AND PROPRIETARY RIGHTS.

Our success depends, in part, on our ability to obtain U.S. and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate our business without infringing the proprietary rights of third parties. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under such patents are still developing and there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. The patent position of a biotechnology firm is highly uncertain and involves complex legal and factual questions. We cannot assure you that any existing or future patents issued to, or licensed by, us will not subsequently be challenged, infringed upon, invalidated or circumvented by others. As a result, although we, together with our subsidiaries, are either the owner or licensee to 24 U.S. patents and to 19 U.S. patent applications now pending, and 8 European patents and 15 European patent applications, we cannot assure you that any additional patents will issue from any of the patent applications owned by, or licensed to, us. Furthermore, any rights that we may have under issued patents may not provide us with significant protection against competitive products or otherwise be commercially viable.

Our patents for the following technologies expire in the years and during the date ranges indicated below:

- 5% amlexanox paste in 2011

- Zindaclin(R) and Residerm(R) between 2007 and 2011

- OraDisc(TM) in 2020

- AP5280 in 2021

- AP5346 in 2021

- Mucoadhesive technology, patents are pending

- Vitamin mediated technology between 2004 and 2019

In addition, patents may have been granted to third parties or may be granted covering products or processes that are necessary or useful to the development of our drug candidates. If our drug candidates or processes are found to infringe upon the patents or otherwise impermissibly utilize the intellectual property of others, our development, manufacture and sale of such drug candidates could be severely restricted or prohibited. In such event, we may be required to obtain licenses from third parties to utilize the patents or proprietary rights of others. We cannot assure you that we will be able to obtain such licenses on acceptable terms, if at all. If we become involved in litigation regarding our intellectual property rights or the intellectual property rights of others, the potential cost of such litigation, regardless of the strength of our legal position, and the potential damages that we could be required to pay could be substantial.

OUR BUSINESS COULD SUFFER IF WE LOSE THE SERVICES OF, OR FAIL TO ATTRACT, KEY PERSONNEL.

We are highly dependent upon the efforts of our senior management and scientific team, including our President and Chief Executive Officer, Kerry Gray. The loss of the services of one or more of these individuals could delay or prevent the achievement of our research, development, marketing, or product commercialization objectives. While we have employment agreements with Mr. Gray and David Nowotnik, PhD our Senior Vice President Research and Development, their employment may be terminated by them or us at any time. Mr. Gray's and Dr. Nowotnik's agreements expire within one year and are extendable each year on the anniversary date. We do not have employment contracts with our other key personnel. We do not maintain any "key-man" insurance policies on any of our key employees and we do not intend to obtain such insurance. In addition, due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific and technical personnel. In view of the stage of our development and our research and development programs, we have restricted our hiring to research scientists and a small administrative staff and we have made only limited investments in manufacturing, production, sales or regulatory compliance resources. There is intense competition among major pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions for qualified personnel in the areas of our activities, however, and we may be unsuccessful in attracting and retaining these personnel.

OWNERSHIP OF OUR SHARES IS CONCENTRATED, TO SOME EXTENT, IN THE HANDS OF A FEW INVESTORS WHICH COULD LIMIT THE ABILITY OF OUR OTHER STOCKHOLDERS TO INFLUENCE THE DIRECTION OF THE COMPANY.

Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.) and Heartland Advisors, Inc. each beneficially owned approximately 12.0% and 11.1%, respectively, of our

common stock as of December 31, 2004. Accordingly, they collectively may have the ability to significantly influence or determine the election of all of our directors or the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of our other stockholders.

PROVISIONS OF OUR CHARTER DOCUMENTS COULD DISCOURAGE AN ACQUISITION OF OUR COMPANY THAT WOULD BENEFIT OUR STOCKHOLDERS AND MAY HAVE THE EFFECT OF ENTRENCHING, AND MAKING IT DIFFICULT TO REMOVE, MANAGEMENT.

Provisions of our Certificate of Incorporation, By-laws and Stockholders Rights Plan may make it more difficult for a third party to acquire control of our company, even if a change in control would benefit our stockholders. In particular, shares of our preferred stock may be issued in the future without further stockholder approval and upon such terms and conditions, and having such rights, privileges and preferences, as our Board of Directors may determine, including, for example, rights to convert into our common stock. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any of our preferred stock that may be issued in the future. The issuance of our preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire control of us. This could limit the price that certain investors might be willing to pay in the future for shares of our common stock and discourage these investors from acquiring a majority of our common stock. Further, the existence of these corporate governance provisions could have the effect of entrenching management and making it more difficult to change our management.

AMEX LISTING REQUIREMENTS.

Our common stock is presently listed on the American Stock Exchange under the symbol AKC. All companies listed on the American Stock Exchange are required to comply with certain continued listing standards, including corporate governance requirements, maintaining stockholders' equity at required levels, obtaining shareholder approvals for certain transactions, share price requirements and other rules and regulations of the American Stock Exchange. If we are unable to remedy any listing standard noncompliance with the American Stock Exchange under its regulations and within the required time frames for such remediation, or

otherwise regain compliance or obtain shareholder approval for any transaction requiring approval, we cannot assure you that our common stock will continue to remain eligible for listing on the American Stock Exchange. In the event that our common stock is delisted from the American Stock Exchange its market value and liquidity could be materially adversely affected.

SUBSTANTIAL SALES OF OUR COMMON STOCK COULD LOWER OUR STOCK PRICE.

The market price for our common stock could drop as a result of sales of a large number of our presently outstanding shares our shares that we may issue or be obligated to issue in the future. All of the 15,524,734 shares of our common stock that are outstanding as of March 15, 2005, are unrestricted and freely tradable or tradable pursuant to a resale registration statement or under Rule 144 of the Securities Act.

FAILURE TO ACHIEVE AND MAINTAIN EFFECTIVE INTERNAL CONTROLS COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR BUSINESS.

Effective internal controls are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our operating results could be harmed. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

While we continue to evaluate and improve our internal controls, we cannot be certain that these measures will ensure that we implement and maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

We have completed documenting and testing our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting and a report by our independent registered public accounting firm addressing these assessments. For the year ended December 31, 2004, our management has determined that our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Please refer to management's annual report on internal control over financial reporting, and the report by Grant Thornton LLP, which appear later in this report. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in our reported financial information, which could have a material adverse effect on our stock price.

ITEM 2. PROPERTIES

We maintain one facility of approximately 17,000 square feet for administrative offices and laboratories in Dallas, Texas. We have a lease agreement for the facility, which terminates in March 2006. Adjacent space may be available for expansion which we believe would accommodate growth for the foreseeable future.

Our subsidiary, Access Pharmaceuticals Australia Pty. Limited, leases approximately 7,000 square feet for offices and laboratories in Sydney, New South Wales, Australia.

We believe that our existing properties are suitable for the conduct of our business and adequate to meet our present needs.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

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

Not applicable.

EXECUTIVE OFFICERS

Mr. Kerry P. Gray, 52, has been our President and Chief Executive Officer and a director since January 1996. Prior to such time, from June 1993, Mr. Gray served as President and Chief Executive Officer of Access Pharmaceuticals, Inc., a private Texas corporation. Previously, Mr. Gray served as Vice President and Chief Financial Officer of PharmaSciences, Inc., a company he co-founded to acquire technologies in the drug delivery area. From May 1990 to August 1991, Mr. Gray was Senior Vice President, Americas, Australia and New Zealand of Rhone-Poulenc Rorer, Inc. Prior to the Rorer/Rhone Poulenc merger, he had been Area Vice President Americas of Rorer International Pharmaceuticals. Previously, from January 1986 to May 1988, he was Vice President, Finance of Rorer International Pharmaceuticals, having served in that same capacity for the Revlon Health Care Group of companies before their acquisition by Rorer Group. Between 1975 and 1985, he held various senior financial positions with the Revlon Health Care Group.

David P. Nowotnik, Ph.D., 56, has been Senior Vice President Research and Development since January 2003 and had been Vice President Research and Development from 1998. From 1994 until 1998, Dr. Nowotnik had been with Guilford Pharmaceuticals, Inc. in the position of Senior Director, Product Development and was responsible for a team of scientists developing polymeric controlled-release drug delivery systems. From 1988 to 1994 he was with Bristol-Myers Squibb researching and developing technetium radiopharmaceuticals and MRI contrast agents. From 1977 to 1988 he was with Amersham International leading the project which resulted in the discovery and development of Ceretec.

Mr. Stephen B. Thompson, 51, has been Vice President since 2000 and our Chief Financial Officer since 1996. From 1990 to 1996, he was Controller and Administration Manager of Access Pharmaceuticals, Inc., a private Texas corporation. Previously, from 1989 to 1990, Mr. Thompson was Controller of Robert E. Woolley, Inc. a hotel real estate company where he was responsible for accounting, finances and investor relations. From 1985 to 1989, he was Controller of OKC Limited Partnership, an oil and gas company where he was responsible for accounting, finances and SEC reporting. Between 1975 and 1985 he held various accounting and finance positions with Santa Fe International Corporation.

PART II

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

PRICE RANGE OF COMMON STOCK AND DIVIDEND POLICY

Our common stock has traded on the American Stock Exchange, or AMEX, since March 30, 2000 under the trading symbol AKC. The following table sets forth, for the periods indicated, the high and low closing prices for our common stock as reported by AMEX for fiscal years 2004 and 2003.

<TABLE>
<CAPTION>

	COMMON STOCK	
	HIGH	LOW
<S>	<C>	<C>
FISCAL YEAR ENDED DECEMBER 31, 2004		
First quarter	$ 6.42	$ 5.09
Second quarter	7.95	5.50
Third quarter	6.33	2.53
Fourth quarter	5.66	2.97
FISCAL YEAR ENDED DECEMBER 31, 2003		
First quarter	$ 2.74	$ 1.75
Second quarter	3.50	1.81
Third quarter	4.40	2.91
Fourth quarter	5.50	3.75

</TABLE>

We have never declared or paid any cash dividends on our preferred stock or common stock and we do not anticipate paying any cash dividends in the foreseeable future. The payment of dividends, if any, in the future is within the discretion of our board of directors and will depend on our earnings, capital requirements and financial condition and other relevant facts. We currently intend to retain all future earnings, if any, to finance the development and growth of our business.

The number of record holders of Access common stock at March 30, 2005 was approximately 5,900. On March 30, 2005, the closing price for the common stock as quoted on the AMEX was $2.50. There were 15,524,734 shares of common stock outstanding at March 20, 2005.

RECENT SALES OF UNREGISTERED SECURITIES

None

EQUITY COMPENSATION PLAN INFORMATION

<TABLE>
<CAPTION>

PLAN CATEGORY	NUMBER OF SECURITIES TO BE ISSUED UPON EXERCISE OF OUTSTANDING OPTIONS WARRANTS AND RIGHTS	WEIGHTED-AVERAGE EXERCISE PRICE OF OUTSTANDING OPTIONS WARRANTS AND RIGHTS	NUMBER OF SECURITIES REMAINING AVAILABLE FOR FUTURE ISSUANCE UNDER EQUITY COMPENSATION PLANS (EXCLUDING SECURITIES REFLECTED IN COLUMN (A))
<S>	<C>	<C>	<C>
Equity compensation plans approved by security holders			
1995 Stock Awards Plan	2,182,181	3.76	129,780
2001 Restricted Stock Plan	126,474	--	38,762
Equity compensation plans not approved by security holders			
2000 Special Stock Option Plan	500,000	2.50	--

</TABLE>

ISSUER PURCHASES OF EQUITY SECURITIES

None

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

The following data has been derived from our audited consolidated financial statements and notes thereto appearing elsewhere in this Form 10-K and prior audited consolidated financial statements of Access and notes thereto. The data should be read in conjunction with the "Selected Financial Data" and Financial Statements and Notes thereto and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this Form 10-K.

<TABLE>
<CAPTION>

	For the Year Ended December 31,				
	2004	2003	2002	2001	2000
<S>	<C>	<C>	<C>	<C>	<C>
CONSOLIDATED STATEMENT OF OPERATIONS AND COMPREHENSIVE LOSS DATA:					
Total revenues	$ 549	$ 1,295	$ 1,147	$ 243	$ 107
Operating loss	(9,079)	(8,213)	(8,700)	(6,308)	(6,058)
Interest and miscellaneous income	226	2,559	594	1,451	972
Interest and other expense	1,385	1,281	1,278	1,170	342
Net loss	(10,238)	(6,935)	(9,384)	(6,027)	(5,428)
COMMON STOCK DATA:					
Net loss per basic and diluted					

common share	$ (0.68)	$ (0.52)	$ (0.72)	$ (0.47)	$ (0.49)
Weighted average basic and diluted common shares outstanding	15,162	13,267	13,104	12,857	11,042

	December 31,				
	2004	2003	2002	2001	2000
CONSOLIDATED BALANCE SHEET DATA:					
Cash, cash equivalents and short term investments	$ 2,261	$ 2,587	$ 9,776	$ 20,126	$ 25,809
Restricted cash	1,284	649	468	600	-
Total assets	11,090	11,811	19,487	25,487	30,526
Deferred revenue	1,199	1,184	1,199	508	551
Convertible notes	13,530	13,530	13,530	13,530	13,530
Total liabilities	17,751	17,636	18,998	16,409	15,522
Total stockholders' equity (deficit)	(6,661)	(5,825)	489	9,078	15,004

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

The following discussion should be read in conjunction with our consolidated financial statements and related notes included in this Form 10-K.

OVERVIEW

We are an emerging pharmaceutical company focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities. We are a Delaware corporation.

Together with our subsidiaries, we have proprietary patents or rights to seven drug delivery technology platforms:

- - synthetic polymer targeted delivery,

- - vitamin mediated targeted delivery,

- - vitamin mediated oral delivery,

- - bioerodible cross-linker technology,

- - mucoadhesive disc technology,

- - hydrogel particle aggregate technology, and

- - Resiferm(R) topical delivery.

In addition, we are marketing in the United States - Aphthasol(R), the first FDA approved product for the treatment of canker sores. We are developing new formulations and delivery forms of amlexanox including mucoadhesive disc delivery and mucoadhesive liquid delivery.

Our amlexanox 5% paste is marketed in the US as Aphthasol(R). Block Drug Company had manufactured the 5% amlexanox paste since the product was approved by the FDA in 1996 in an approved Puerto Rico facility. At such time when we acquired the US rights to Aphthasol(R), we entered into a Supply Agreement whereby Block Drug Company was to produce Aphthasol(R) for us for a defined period of time at its Puerto Rico facility. We were subsequently advised by Block Drug Company that it was unable to comply with the terms of the Supply Agreement and that it would not be able to produce Aphthasol(R) for us. Due to Block Drug Company's production failure, we had sufficient product to supply wholesalers only through June 2003. We selected Contract Pharmaceuticals Ltd. Canada as our new manufacturer of amlexanox 5% paste and it completed full scale production in September 2004. We re-launched Aphthasol(R) in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004.

Since our inception, we have devoted our resources primarily to fund our

research and development programs. We have been unprofitable since inception and to date have received limited revenues from the sale of products. We cannot assure you that we will be able to generate sufficient product revenues to attain profitability on a sustained basis or at all. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance. As of December 31, 2004, our accumulated deficit was $64,465,000.

Subsequent to the end of the period being reported on (December 31, 2004), the Company finalized an agreement with Cornell Capital Partners and Highgate House Funds providing funding in the form of a Secured Convertible Debenture for net proceeds of approximately $2,360,000, and an Equity Distribution Agreement under which the Company can draw up to $15,000,000 in working capital over a 2-year period (see further discussion under Liquidity).

On February 24, 2004 we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of $5.40. We received gross proceeds of $9,663,000 from this sale and had expenses of $615,000. The investors also received 5 year warrants at an exercise price of $7.10 per share to purchase 447,344 shares of our common stock and the placement agents received warrants in the offering at an exercise price of $5.40 per share to purchase 156,481 shares of our common stock.

RESULTS OF OPERATIONS

COMPARISON OF YEARS ENDED DECEMBER 31, 2004 AND 2003

Our licensing revenue in 2004 was $104,000, as compared to licensing revenue of $729,000 in 2003, a decrease of $625,000 due to one time initial licensing fees in 2003. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2004 and 2003 was from several agreements including agreements related to various amlexanox projects and Residerm(R).

Product sales of Aphthasol(R) totaled $351,000 in 2004, as compared to product sales of $532,000 in 2003. Sales were limited in 2004 due to a supply interruption of the product. Supplies were manufactured in the third quarter of 2004 and sales commenced in late September 2004.

Royalty income for 2004 was $94,000 as compared to $34,000 in 2003, an increase of $60,000 due to higher sales of Zindaclin(R) in additional countries.

Our total research spending for the year ended December 31, 2004 was $5,417,000, as compared to $6,096,000 in 2003, a decrease of $679,000. The decrease in expenses was the result of:

- lower clinical development costs ($622,000) for our OraDisc(TM) A clinical trial which was completed in 2003;

- lower costs for the AP5280 and AP5346 polymer platinate clinical trials ($374,000) of which the AP5280 trial was completed in 2003; and

- other net decreases ($201,000).

These decreases were partially offset by:

- higher production and testing costs for Aphthasol(R) and start-up costs for OraDisc(TM) A ($117,000);

- higher scientific salary and salary related expenses due to additional staff ($269,000); and

- higher expenses in our Australian operations ($132,000).

Our cost of product sales was $239,000 for 2004 as compared to $277,000 in 2003, a decrease of $38,000. The decrease in the cost of product sales was due to reduced Aphthasol(R) sales in 2004 due to the supply interruption.

Our total general and administrative expenses were $3,199,000 for 2004, an increase of $685,000 over 2003 expenses of $2,514,000, due to:

- higher professional fees and expenses ($339,000) principally due

to increased accounting and legal fees associated with compliance with the Sarbanes-Oxley Act, new contracts and legal proceedings;

- higher business consulting expenses for new business development activities ($88,000);

- higher fees for a healthcare consultant review ($133,000);

- higher patent and license expenses ($51,000);

- higher salary and related expense ($63,000); and

- other net increases ($11,000).

Depreciation and amortization was $773,000 in 2004 as compared to $621,000 in 2003, an increase of $152,000 due to the impairment of a license which is no longer effective ($109,000) and from the acquisition of new capital equipment ($43,000).

Our loss from operations in 2004 was $9,079,000 as compared to a loss of $8,213,000 in 2003.

Interest and miscellaneous income was $226,000 for 2004 as compared to $2,559,000 for 2003, a decrease of $2,333,000. The decrease in miscellaneous income of $2,280,000 was due to a one time payment associated with a

settlement agreement with Block Drug Company in 2003 and a decrease in interest income due to lower cash balances and lower interest rates in 2004 as compared with 2003.

Interest and miscellaneous expense was $1,385,000 for 2004 as compared to $1,281,000 for the same period in 2003, an increase of $104,000. The expense to record an impairment in investment $112,000 and the change in interest expense was $8,000.

Net loss for 2004 was $10,238,000, or a $0.68 basic and diluted loss per common share compared with a loss of $6,935,000, or a $0.52 basic and diluted loss per common share, for 2003.

COMPARISON OF YEARS ENDED DECEMBER 31, 2003 AND 2002

Our licensing revenue in 2003 was $729,000, as compared to licensing revenue of $853,000 in 2002, a decrease of $124,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2003 and 2002 was from several agreements, including agreements related to various amlexanox projects and Residerm(R).

Product sales of Aphthasol(R) totaled $532,000 in 2003, as compared to product sales of $194,000 in 2002. Our first sales were recorded in December 2002. As a result of the Aphthasol(R) supply situation discussed above, there were no product sales of Aphthasol(R) between July 2003 and August 2004.

In 2002 we had a research and development agreement which provided $89,000 in revenue. The agreement expired in 2002 and we had no such revenue in 2003.

Royalty income for 2003 was $34,000 as compared to $11,000 in 2002, an increase of $23,000.

Our total research spending for the year ended December 31, 2003 was $6,096,000, as compared to $7,024,000 in 2002, a decrease of $928,000. The decrease in expenses was the result of:

- lower clinical development costs ($812,000) for the amlexanox OraDisc(TM) project; and

- lower development and clinical development costs for our polymer platinate project ($773,000).

These decreases were offset by:

- higher salary and salary related expenses due to additional staff ($278,000);

- higher expenses due to the full year impact of our Australian operations ($254,000);

- higher internal lab costs due to the additional staff and projects ($102,000); and

- other net increases ($23,000).

Our cost of product sales was $277,000 for 2003 as compared to $107,000 in 2002. The commencement of our Aphthasol(R) sales began in the fourth quarter of 2002.

Our total general and administrative expenses were $2,514,000 for 2003, an increase of $237,000 over 2002 expenses of $2,277,000, due to:

- higher professional fees and expenses ($81,000);

- higher shareholder-investor relations expenses ($144,000);

- higher patent and license expenses ($60,000);

- higher salary and related expense ($50,000); and

- higher rent expenses ($31,000).

These increases were offset by lower withholding taxes on foreign revenues ($129,000).

Depreciation and amortization was $621,000 in 2003 as compared to $439,000 in 2002, an increase of $182,000 primarily resulting from the acquisition of new capital equipment and a full year of amortization of acquired patents.

Our loss from operations in 2003 was $8,213,000 as compared to a loss of $8,700,000 in 2002.

Our interest and miscellaneous income was $2,559,000 for 2003 as compared to $594,000 for 2002, an increase of $1,965,000. The increase in miscellaneous income of $2,280,000 was due to a one time settlement agreement with Block Drug Company relating to Block's contractual obligation to supply Aphthasol(R) to us. Pursuant to the settlement, Block made a onetime cash payment to us and we were also relieved of certain future payment obligations to Block under the Asset Sale Agreement pursuant to which we purchased from Block the assets relating to amlexanox. Under the settlement agreement, Block was relieved of its obligation to supply amlexanox to us. The increase in interest and miscellaneous income was partially offset by a decrease in interest income due to lower cash balances and lower interest rates in 2003 as compared with 2002.

Interest expense was $1,281,000 for 2003 as compared to $1,278,000 for the same period in 2002, an increase of $3,000.

Net loss for 2003 was $6,935,000, or a $0.52 basic and diluted loss per common share compared with a loss of $9,384,000, or a $0.72 basic and diluted loss per common share, for 2002.

LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through private sales of common stock and convertible notes and our principal source of liquidity is cash and cash equivalents. Contract research payments, licensing fees and milestone payments from corporate alliances and mergers have also provided funding for operations. As of December 31, 2004 our cash and cash equivalents and short-term investments were $2,261,000 and our working capital was $(7,788,000). Our working capital at December 31, 2004 represented a decrease of $8,994,000 as compared to our working capital as of December 31, 2003 of $1,206,000. The decrease in working capital was due mainly to $8,030,000 of convertible notes that is coming due within twelve months and by the loss from operations for the twelve months ended December 31, 2004 offset by a private placement of common stock and warrants raising $9.1 million of net proceeds.

As of December 31, 2004, the Company had a working capital deficit of approximately $7,788,000. As of that date, the Company did not have enough capital to achieve its near, medium or long-term goals. Subsequent to that date, the Company reached an agreement which management believes will provide sufficient capital to achieve its short-term goals, and depending upon results

may provide sufficient capital to meet its long-term goals.

As of March 30, 2005 the Company executed a Standby Equity Distribution Agreement (SEDA) with Cornell Capital Partners. Under the SEDA, the Company may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to $15,000,000. The purchase price for the shares is equal to their market price, which is defined in the SEDA as 98% of the lowest volume weighted average price of the common stock during a specified period of trading days following the date notice is given by the Company that it desires to access the SEDA. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the Equity Line of Credit. The amount of each draw down is subject to a maximum amount of $1,000,000. The terms of the SEDA do not allow us to make any draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our outstanding shares of common stock. The Company believes that because of the ability of Cornell Capital to sell shares under a registration statement and as a result of Cornell Capital's business model Access does not believe that Cornell would accumulate 9.9% of the outstanding common stock of the Company. Upon closing of the transaction, Cornell Capital Partners will receive a one-time commitment fee of 146,500 shares of the Company's common stock. On the same date, the Company entered into a Placement Agent Agreement in escrow with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the Placement Agent Agreement, upon closing of the transaction the Company will pay a one-time placement agent fee of 3,500 shares of common stock.

In addition, as of March 30, 2005, the Company executed a Securities Purchase Agreement with Cornell Capital Partners and Highgate House Funds. Under the Securities Purchase Agreement, upon closing Cornell Capital Partners and Highgate House Funds are obligated to purchase an aggregate of $2,633,000 principal amount of Secured Convertible Debentures from the Company (net proceeds to the Company of $2,360,000). The Secured Convertible Debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the Secured Convertible Debenture has not been converted to common stock. The Secured Convertible Debenture is convertible into the Company's common stock at the holder's option any time up to maturity at a conversion price equal to $4.00. The Secured Convertible Debentures are secured by all of the assets of the Company. The Company has the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, the Company is required to issue to the holders an aggregate of 50,000 shares of common stock of the Company.

Each of the SEDA, Security Purchase Agreement and related agreements are in escrow pending our filing of this Form 10K and issuance of shares of common stock required to be issued under the agreement.

On February 24, 2004 we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of $5.40. We received gross proceeds of $9,663,000 from this sale and had expenses of $647,000. The investors also received 5 year warrants at an exercise price of $7.10 per share to purchase 447,344 shares of our common stock and the placement agents received warrants in the offering at an exercise price of $5.40 per share to purchase 156,481 shares of our common stock.

We have also issued an aggregate of $13,530,000 of convertible notes, which are due in two parts -$8,030,000 is due on September 13, 2005 and $5,500,000 is due on September 13, 2008. The notes which bear interest at a rate of 7.7% per annum with $1,042,000 of interest due annually on each September 13, may convert to common stock at a conversion price of $5.50 per share. Should the holders of the notes not elect to convert them to common stock, or if we are not able to force the conversion of the notes by their terms, we must repay the amounts on the due dates. A failure to restructure our existing convertible notes or obtain necessary additional capital in the future could jeopardize our operations. We do not have sufficient funds to repay our convertible notes at their maturity. We may not be able to restructure the convertible notes or obtain additional financing to repay them on terms acceptable to us, if at all. If we raise additional funds by selling equity securities, the relative equity ownership of our existing investors would be diluted and the new investors could obtain terms more favorable than previous investors. A failure to restructure our convertible notes or obtain additional funding to repay the convertible notes and support our working capital and operating requirements, could cause us to be in default of our convertible notes and prevent us from making expenditures that are needed to allow us to maintain our operations.

We have generally incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of December 31, 2004 of $64,465,000. We expect that our existing capital resources together with anticipated licensing revenues and royalties will be adequate to fund our current level of operations for twelve months excluding any obligation to repay the convertible notes and the debt service on the convertible notes. We cannot assure you that we will ever be able to generate significant product revenue or achieve or sustain profitability. We currently do not have the cash resources to repay our Convertible Notes due in September 2005. Our financing plan through the use of the SEDA or other sales of equity are expected to provide the resources to repay such notes.

We plan to expend substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products, including research and development with respect to our acquired and developed technology. Our future capital requirements and adequacy of available funds will depend on many factors, including:

- the ability to convert, repay or restructure our outstanding convertible notes and debentures;
- the successful commercialization of amlexanox and Zindaclin(R);
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- successful regulatory filings.

We have devoted substantially all of our efforts and resources to research and development conducted on our own behalf. The following table summarizes research and development spending by project category (in thousands), which spending includes, but is not limited to, payroll and personnel expense, lab supplies, preclinical expense, development cost, clinical trial expense, outside manufacturing expense and consulting expense:

<TABLE>
<CAPTION>

	Twelve Months ended December 31,		
Project	2004	2003	Inception To Date (1)
<S>	<C>	<C>	<C>
Polymer Platinate (AP5280 and AP5346)	$ 2,330	$ 2,559	$ 15,111
OraDisc(TM)	1,084	1,387	7,307
Bioerodible Hydrogel Technology and Nanoparticles and Nanoparticle Networks	951	978	3,299
Vitamin Mediated Targeted Delivery	748	614	1,703
Mucoadhesive Liquid			

Technology (MLT)	51	34	1,480
Others (2)	253	524	5,020
Total	$ 5,417	$ 6,096	$ 33,920

</TABLE>

(1) Cumulative spending from inception through December 31, 2004.

(2) The following projects are among the ones included in this line item: Carbohydrate targeting, amlexanox cream and gel and other related projects.

Due to uncertainties and certain of the risk factors described above, including those relating to our ability to successfully commercialize our drug candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes, government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, market acceptance of our products and protection of our intellectual property, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risk factors above, including without limitation those relating to the uncertainty of the success of our research and development activities and our ability to obtain necessary additional capital to fund operations in the future. As discussed in such risk factors, delays in our research and development efforts and any inability to raise additional funds could cause us to eliminate one or more of our research and development programs.

We plan to continue our policy of investing available funds in certificates of deposit, money market funds, government securities and investment-grade interest-bearing securities. We do not invest in derivative financial instruments.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

The preparation of our financial statements in conformity with accounting principles generally accepted in the United State of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reported period. In applying our accounting principles, we must often make individual estimates and assumptions regarding expected outcomes or uncertainties. As you might expect, the actual results or outcomes are often different than the estimated or assumed amounts. These differences are usually minor and are included in our consolidated financial statements as soon as they are known. Our estimates, judgments and assumptions are continually

evaluated based on available information and experience. Because of the use of estimates inherent in the financial reporting process, actual results could differ from those estimates.

REVENUE

Revenue associated with up-front license, technology access and research and development funding payments under collaborative agreements is recognized ratably over the performance period of the agreement. Determination of the performance period involves judgment on management's part.

ASSET IMPAIRMENT

On January 1, 2002, we adopted SFAS 142, "Goodwill and Other Intangible Assets." Upon adoption, we performed a transitional impairment test on our recorded intangible assets that consisted primarily of acquisition related goodwill and license intangibles. We also performed an annual impairment test in the fourth quarter of 2004. The analysis resulted in no goodwill impairment charge in 2004. We will be required to perform this test on at least an annual basis.

Our intangible assets at December 31, 2004 consist primarily of goodwill, patents acquired in acquisitions and licenses, which were recorded at fair value on the acquisition date.

Based on an assessment of our accounting policies and underlying judgments and uncertainties affecting the application of those policies, we believe that our consolidated financial statements provide a meaningful and fair perspective of us. We do not suggest that other general factors, such as those discussed elsewhere in this report, could not adversely impact our consolidated financial position, results of operations or cash flows. The impairment test involves judgment on the part of management as to the value of goodwill, licenses and intangibles.

OFF-BALANCE SHEET TRANSACTIONS

None

CONTRACTUAL OBLIGATIONS

The Company's contractual obligations as of December 31, 2004 are set forth below.

<TABLE>
<CAPTION>

	Payment Due by Period		
	Total	Less Than 1 Year	1-3 Years
<S>	<C>	<C>	<C>
Long-Term Debt Obligations	$ 13,992,000	$ 8,335,000	$ 5,657,000
Capital Lease Obligations	118,000	82,000	36,000
Total	$ 14,110,000	$ 8,417,000	$ 5,693,000

</TABLE>

ITEM 7(a). QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our excess cash and short-term investments in certificates of deposit, corporate securities with high quality ratings, and U.S. government securities. These investments are not held for trading or other speculative purposes. These financial investment securities all mature in 2005 and 2006 and their estimated fair value approximates cost. Changes in interest rates affect the investment income we earn on our investments and, therefore, impact our cash flows and results of operations. A hypothetical 50 basis point decrease in interest rates would result in a decrease in annual interest income and a corresponding increase in net loss of approximately $24,000. The estimated effect assumes no changes in our short-term investments at December 31, 2004. We do not believe that we

are exposed to any market risks, as defined. We are not exposed to risks for changes in commodity prices, or any other market risks.

ITEM 8. FINANCIAL AND SUPPLEMENTARY DATA

Financial statements required by this Item are incorporated in this 10-K on pages F-1 through F-20. Reference is made to Item 15 of this Form -10-K.

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

None.

ITEM 9(A). CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. Our chief executive officer and our chief financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-(e) of the Securities and Exchange Act of 1934) as

of the end of the period covered by this annual report, have concluded that as of that date, our disclosure controls and procedures were effective in ensuring that information required to be disclosed by us in this annual report is accumulated and communicated by our management, to allow timely decisions regarding required disclosure.

(b) Management's report on internal control over financial reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rules 13a-(f). Management assessed the effectiveness of our internal controls over financial reporting using criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in - "Internal Control Integrated Framework". Based on our evaluation using those criteria, our management concluded that our internal control over financial reporting was effective as of December 31, 2004. Our management's assessment of the effectiveness of our internal control over financial reporting as of December 31, 2004, has been audited by Grant Thornton LLP, an independent registered public accounting firm, as stated in their attestion report which is included in this annual report on Form 10-K in Item 15.

(c) Changes in internal controls. There were no changes in our internal controls during the fourth quarter of 2004 that have materially affected, or are reasonably likely to material affect, our internal controls.

(d) Management's response to Report of Independent Registered Public Accounting Firm. Our auditors have reached a different conclusion on our internal control over financial reporting than we have reached. Their conclusion is that we have two material weaknesses in the areas of segregation of duties and as a result of an aggregation of three separate significant deficiencies where the effectiveness of the controls are dependent on segregation of duties, as set forth in their attestation report. Their conclusion also points out that "these material weaknesses did not result in any adjustments to the annual or interim consolidated financial statements ..." and that "this report does not affect (their) report dated March 31, 2005" reflecting their opinion on the financial statements.

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our principal executive and principal financial officers, and effected by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles including those policies and procedures necessary to prepare, authorize, approve, maintain, record and report accurately.

Adequate segregation of duties is an important consideration in determining if a company's control activities are effective in achieving the objectives of internal control. A fundamental element of internal

control is the segregation of certain key duties. The basic idea underlying segregation of duties is that no employee or group should be in a position both to perpetrate and to conceal errors or fraud in the normal course of their duties.

An essential feature of segregation of duties/responsibilities within an organization is that no one employee or group of employees has exclusive control over any transaction or group of transactions. In addition, a control over the processing of a transaction should not be performed by the same individual who is responsible for recording or reporting the transaction.

Based on the size of the Company, the complexity of our operations, the number of transactions and the internal controls in place management believes that the resources that were devoted to financial reporting in 2004 were appropriate. We do not expect that our internal control over financial reporting will prevent or detect all error and all fraud. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Continuous evaluation of controls is required.

Planned Remediation Action to Address Internal Control Weakness Identified by External Auditors

Based on the above criteria the external auditors have determined that proper segregation of duties does not exist within the accounting and finance area. While the Company considers that there may be a perceived lack of segregation of duties within the business, management believes that sufficient controls are in place, including subsequent reviews of transactions and results, budget versus actual comparisons and ethical programs, that would limit the potential for a misstatement of the financial statements that is more than inconsequential and the current internal control environment provides reasonable assurance that material misstatements in the financial statements would be prevented or detected on a timely basis by employees in the normal course of performing their assigned functions.

Furthermore, management believes there is adequate segregation of duties within the business and given the history of the individuals above with the business, believes that the chances of collusion resulting in financial reporting fraud would be more than remote. In 2004 and in prior periods there have been no incidences where it has been necessary to make material adjustments to the annual or interim consolidated financial statements due to breakdown in our internal controls.

However, the Company recognizes that this is a perceived material weakness and is taking the necessary steps to mitigate this risk. Management and the Audit Committee has considered the need for ongoing monitoring of internal controls under Sarbanes-Oxley as well as strengthening the internal controls of the business by the engagement of an outside accounting/finance consulting firm to perform quarterly procedures designed to assist in the maintaining and monitoring of an effective control environment and to mitigate the risk related to a lack of segregation of duties between senior accounting/finance personnel.

Standing alone, Sarbanes-Oxley requires quarterly and annual assessments of the internal control structure and reporting function. As processes change, management is required to update documentation and perform adequate levels of testing to provide assurance that existing and any new procedure is functioning appropriately. Furthermore, as the Company grows documentation requirements are expected to be ongoing so the Company will be making the documentation and internal control process improvement an overriding theme.

The consulting firm is expected to report and take instructions directly from the Audit Committee although management will be involved in assisting in determining the scope of the quarterly and annual procedures. Terms and conditions of this engagement are still under consideration.

ITEM 9(B). OTHER INFORMATION

As of March 30, 2005 the Company executed a Standby Equity Distribution Agreement (SEDA) with Cornell Capital Partners. Under the SEDA, the Company may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to $15,000,000. The purchase price for the shares is equal to their market price, which is defined in the SEDA as 98% of the lowest volume weighted average price of the common stock during a specified period of trading days following the date notice is given by the Company that it desires to access the SEDA. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the Equity Line of Credit. The amount of each draw down is subject to a maximum amount of $1,000,000. The terms of the SEDA do not allow us to make any draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our outstanding shares of common stock. The Company believes that because of the ability of Cornell Capital to sell shares under a registration statement and as a result of Cornell Capital's business model Access does not believe that Cornell would accumulate 9.9% of the outstanding common stock of the Company. Upon closing of the transaction, Cornell Capital Partners will receive a one-time commitment fee of 146,500 shares of the Company's common stock. On the same date, the Company entered into a Placement Agent Agreement in escrow with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the Placement Agent Agreement, upon closing of the transaction the Company will pay a one-time placement agent fee of 3,500 shares

of common stock.

In addition, as of March 30, 2005, the Company executed a Securities Purchase Agreement with Cornell Capital Partners and Highgate House Funds. Under the Securities Purchase Agreement, upon closing Cornell Capital Partners and Highgate House Funds are obligated to purchase an aggregate of $2,633,000 principal amount of Secured Convertible Debentures from the Company (net proceeds to the Company of $2,360,000). The Secured Convertible Debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the Secured Convertible Debenture has not been converted to common stock. The Secured Convertible Debenture is convertible into the Company's common stock at the holder's option any time up to maturity at a conversion price equal to $4.00. The Secured Convertible Debentures are secured by all of the assets of the Company. The Company has the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, the Company is required to issue to the holders an aggregate of 50,000 shares of common stock of the Company.

Each of the SEDA, Security Purchase Agreement and related agreements are in escrow pending our filing of this Form 10K and issuance of shares of common stock required to be issued under the agreement.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY

DIRECTORS. The information required by this item with respect to directors (including with respect to the audit committee of our Board of Directors) and reports of beneficial ownership will be contained in our definitive Proxy Statement ("Proxy Statement") for our 2005 Annual Meeting of Stockholders to be held on May 13, 2005 and is incorporated herein by reference. We will file the Proxy Statement with the Securities and Exchange Commission not later than April 29, 2005.

CODE OF ETHICS. We have adopted a Code of Business Conduct and Ethics (the "Code") that applies to all of our employees (including executive officers) and directors. The Code is available on our website at www.accesspharma.com. We intend to satisfy the disclosure requirement regarding any waiver of a provision of the Code applicable to any executive officer or director, by posting such information on such website. Access shall provide to any person without charge, upon request, a copy of the Code. Any such request must be made in writing to Access, c/o Investor Relations, 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207.

Our corporate governance guidelines and the charters of the audit committee, compensation committee and nominating and corporate governance committee of the Board of Directors are available on our website at www.accesspharma.com. Access shall provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to Access, c/o Investor Relations, 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

PART IV

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

<TABLE>
<CAPTION>
a. Financial Statements and Exhibits — Page

</TABLE>

2. Financial Statement Schedules

No financial statement schedules are included because they are not required or the information is included in the financial statements or notes thereto.

3. Exhibits

<TABLE>
<CAPTION>
Exhibit Number

<S> <C>

2.1 Amended and Restated Agreement of Merger and Plan of Reorganization between Access Pharmaceuticals, Inc. and Chemex Pharmaceuticals, Inc., dated as of October 31, 1995 (Incorporated by reference to Exhibit A of the our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)

3.0 Articles of incorporation and bylaws:

3.1 Certificate of Incorporation (Incorporated by Reference to Exhibit 3(a) of our Form 8-B dated July 12, 1989, Commission File Number 9-9134)

3.2 Certificate of Amendment of Certificate of Incorporation filed August 21, 1992

3.3 Certificate of Merger filed January 25, 1996. (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)

3.4 Certificate of Amendment of Certificate of Incorporation filed January 25, 1996. (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)

3.5 Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 of our Form 10-Q for the quarter ended June 30, 1996)

3.6 Certificate of Amendment of Certificate of Incorporation filed July 18, 1996. (Incorporated by reference to Exhibit 3.8 of our Form 10-K for the year ended December 31, 1996)

3.7 Certificate of Amendment of Certificate of Incorporation filed June 18, 1998. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended June 30, 1998)

3.8 Certificate of Amendment of Certificate of Incorporation filed July 31, 2000. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended March 31, 2001)

3.9 Certificate of Designations of Series A Junior Participating Preferred Stock filed November 7, 2001 (Incorporated by reference to Exhibit 4.1.h of our Registration Statement on Form S-8, dated December 14, 2001, Commission File No. 333-75136)

10.0 Material contracts:

10.1 Irrevocable Assignment of Proprietary Information with Dr. Charles G.
</TABLE>

	Smith (Incorporated by reference to Exhibit 10.6 of our Form 10-K for the year ended December 31, 1991)
10.2	Asset Purchase and Royalty Agreement between Block Drug Company, Inc. and us dated June 7, 1995 (Incorporated by reference to Exhibit 10.28 of our Form 10-Q for the quarter ended June 30, 1995)

</TABLE>

3.0 Exhibits (continued)

<TABLE>
<CAPTION>

Exhibit Number	
<S>	<C>
*10.3	1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
10.4	Patent Purchase Agreement dated April 5, 1994 between David F. Ranney and Access Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.16 of the our Form 10-K for the year ended December 31, 1995)
10.5	First Amendment to Patent Purchase Agreement dated January 23, 1996 between David F. Ranney and us (Incorporated by reference to Exhibit 10.17 of our Form 10-K for the year ended December 31, 1995)
10.6	Lease Agreement between Pollock Realty Corporation and us dated July 25, 1996 (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended September 30, 1996)
10.7	Platinate HPMA Copolymer Royalty Agreement between The School of Pharmacy, University of London and the Company dated November 19, 1996 (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended September 30, 1996)
10.8	Agreement of Merger and Plan of Reorganization, dated May 23, 1997 among us, Access Holdings, Inc and Tacora Corporation (Incorporated by reference to Exhibit 10.11 of the Company's Form 10-K for the year ended December 31, 1997)
10.9	License Agreement between ProStrakan Limited and us dated February 26, 1998 (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.12 of our Form 10-Q for the quarter ended March 31, 1998)
10.10	Agreement between us and Block Drug Company, Inc. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.13 of our Form 10-Q for the quarter ended June 30, 1998)
*10.11	Employment Agreement of Mr. Kerry P. Gray (Incorporated by reference to our Registration Statement on Form SB-2 dated January 11, 1999, Commission File No. 333-62463)
10.12	Letter Agreement between us and David F. Ranney (Incorporated by reference to our Registration Statement on Form SB-2 dated January 11, 1999, Commission File No. 333-62463)
10.13	License Agreement between Block Drug Company and us dated December 21, 1998 (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.11 of our Form 10-K for the year ended December 31, 1998)
10.14	Agreement of Merger and Plan of Reorganization, dated as of February 23, 1999 among us, Access Holdings, Inc. and Virologix Corporation (Incorporated by reference to Exhibit 2.2 of the Company's Form 8-K filed on August 3, 1999)
*10.15	Employment Agreement of David P. Nowotnik, PhD (Incorporated by reference to Exhibit 10.19 of our Form 10-K for the year ended December 31, 1999)
*10.16	401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10K for the year ended December 31, 1999)
*10.17	2000 Special Stock Option Plan and Agreement (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)
10.18	Form of Convertible Note (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)
10.19	Supplemental Lease Agreement between Pollock Realty Corporation and us dated February 9, 2002. (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended June 30, 2002)
10.20	Rights Agreement, dated as of October 31, 2001 between the Registrant and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 99.1 of our Current Report on Form 8-K dated October 19, 2001)

*10.21	2001 Restricted Stock Plan (incorporated by reference to Appendix A of our Proxy Statement filed on April 16, 2001)
10.22	Supplemental Lease Agreement between Pollock Realty Corporation and us dated September 15, 2002. (Incorporated by reference to Exhibit 10.24 of our Form 10-K for the year ended December 31, 2001)
10.23	Amendment to 1995 Stock Option Plan (Incorporated by reference to Exhibit 10.25 of our Form 10-K for the year ended December 31, 2001)

3.0 Exhibits (continued)

Exhibit Number	
10.24	Asset Sale Agreement among BIOA Pty. Limited, Access Pharmaceuticals Australia Pty. Limited, Human Therapeutics Limited and us dated February 26, 2002. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.26 of our Form 10-Q for the quarter ended March 31, 2002)
10.25	Asset Sale Agreement between Block Drug Company, Inc. and us dated July 22, 2002. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.27 of our Form 10-Q for the quarter ended September 30, 2002)
10.26	License and Supply Agreement between Wyeth, acting through its Wyeth Consumer Healthcare Division and us dated January 6, 2004. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.26 of our Form 10-Q for the quarter ended March 31, 2004)
21.	Subsidiaries of the registrant
23.0	Consent of Experts and Counsel
23.1	Consent of Grant Thornton LLP
31.01	Chief Executive Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.02	Chief Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.01	Chief Executive Officer Certification 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

* Management contract or compensatory plan required to be filed as an Exhibit to this Form pursuant to Item 15(c) of the report

SIGNATURES

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

ACCESS PHARMACEUTICALS, INC.

Date March 31, 2005 By: /s/ Kerry P. Gray

Kerry P. Gray
President and Chief Executive Officer

Date March 31, 2005 By: /s/ Stephen B. Thompson

Stephen B. Thompson
Vice President, Chief Financial Officer and Treasurer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Company and in

the capacities and on the dates indicated.

Date March 31, 2005 By: /s/ Kerry P. Gray

Kerry P. Gray
President and Chief Executive
Officer, Director

Date March 31, 2005 By: /s/ Stuart M. Duty

Stuart M. Duty, Director

Date March 31, 2005 By: /s/ J. Michael Flinn

J. Michael Flinn, Director

Date March 31, 2005 By: /s/ Stephen B. Howell

Stephen B. Howell, Director

Date March 31, 2005 By: /s/ Max Link

Max Link, Director

Date March 31, 2005 By: /s/ Herbert H. McDade, Jr.

Herbert H. McDade, Jr., Director

Date March 31, 2005 By: /s/ John J. Meakem

John J. Meakem, Jr., Director

REPORT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM

Board of Directors and
Shareholders of Access Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Access Pharmaceuticals, Inc. (the "Company"), as of December 31, 2004 and 2003, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2004. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. Our audit included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

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

/s/ GRANT THORNTON LLP

Dallas, Texas
March 31, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and
Shareholders of Access Pharmaceuticals, Inc.

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

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

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

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

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. We have identified the following material weaknesses that have not been identified as material weaknesses in management's assessment. These material weaknesses did not result in any adjustments to the annual or interim consolidated financial statements, however; these material weaknesses could result in a material misstatement to future annual or interim consolidated financial statements that would not be prevented or detected.

1. The Company has a limited number of personnel with responsibility for accounting and financial reporting matters. As a result, there is a lack of segregation of duties over the initiation, authorization, recording and reporting of transactions and the preparation and review of financial statements by persons sufficiently independent of the transactions. These segregation of duties issues also extend to the Company's information technology controls whereby the personnel limitations result in individuals having the ability to initiate, approve and record transactions.

2. Our evaluation of the design of the Company's internal controls identified the following significant deficiencies that individually are not considered a

material weakness; however, compensating or mitigating controls to prevent material misstatements occurring as a result of these deficiencies are dependent on adequate segregation of duties. Because of the inadequate segregation of duties present in the Company's control environment, these deficiencies represent, in the aggregate, a material weakness.

- Lack of formal controls to monitor compliance with existing policies, practices and procedures, including within the information technology environment.

- Reliance on undocumented controls to verify the accuracy of transactions and financial reporting.

- Consistency in the performance of manual controls and approvals at the transaction level and review of accounting and financial reporting information used to prepare financial statements.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2004 financial statements, and this report does not affect our report dated March 31, 2005, on those financial statements.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, management's assessment that Access Pharmaceuticals, Inc., maintained effective internal control over financial reporting as of December 31, 2004, is not fairly stated, in all material respects, based on criteria established in Internal Control -- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Access Pharmaceuticals, Inc., has not maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control -- Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

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

/s/ GRANT THORNTON LLP

Dallas, Texas
March 31, 2005

ACCESS PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

<TABLE>
<CAPTION>

	December 31, 2004	December 31, 2003
<S>	<C>	<C>
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,775,000	$ 727,000
Short term investments, at cost	486,000	1,860,000
Accounts and other receivables	791,000	1,149,000
Inventory	125,000	185,000
Prepaid expenses and other current assets	1,093,000	898,000
Total current assets	4,270,000	4,819,000
Property and equipment, net	1,040,000	1,004,000

Debt issuance costs, net	130,000	313,000
Patents, net	2,315,000	2,652,000
Licenses, net	125,000	367,000
Goodwill, net	1,868,000	1,868,000
Restricted cash and other assets	1,342,000	788,000
Total assets	$ 11,090,000	$ 11,811,000

LIABILITIES AND STOCKHOLDERS' DEFICIT

Current liabilities		
Accounts payable and accrued expenses	$ 2,131,000	$ 1,780,000
Accrued interest payable	311,000	311,000
Deferred revenues	1,199,000	1,184,000
Current portion of note payable and other future obligations	8,417,000	338,000
Total current liabilities	12,058,000	3,613,000
Long-term obligations for purchased patents	-	211,000
Note payable, net of current portion	193,000	282,000
Convertible notes	5,500,000	13,530,000
Total liabilities	17,751,000	17,636,000
Commitments and contingencies		
Stockholders' deficit		
Preferred stock - $.01 par value; authorized 2,000,000 shares; none issued or outstanding	-	-
Common stock - $.01 par value; authorized 50,000,000 shares; issued, 15,524,734 at December 31, 2004 and 13,397,034 at December 31, 2003	155,000	134,000
Additional paid-in capital	59,010,000	49,597,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Unamortized value of restricted stock grants	(309,000)	(294,000)
Treasury stock, at cost - 819 shares	(4,000)	(4,000)
Accumulated other comprehensive loss	(3,000)	14,000
Accumulated deficit	(64,465,000)	(54,227,000)
Total stockholders' deficit	(6,661,000)	(5,825,000)
Total liabilities and stockholders' deficit	$ 11,090,000	$ 11,811,000

</TABLE>

The accompanying notes are an integral part of these statements.

ACCESS PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

<TABLE>
<CAPTION>

	Year ended December 31,		
	2004	2003	2002
<S>	<C>	<C>	<C>
Revenues			
License revenues	$ 104,000	$ 729,000	$ 853,000
Product sales	351,000	532,000	194,000

Research and development	-	-	89,000
Royalty income	94,000	34,000	11,000
Total revenues	549,000	1,295,000	1,147,000
Expenses			
Research and development	5,417,000	6,096,000	7,024,000
Cost of product sales	239,000	277,000	107,000
General and administrative	3,199,000	2,514,000	2,277,000
Depreciation and amortization	773,000	621,000	439,000
Total expenses	9,628,000	9,508,000	9,847,000
Loss from operations	(9,079,000)	(8,213,000)	(8,700,000)
Other income (expense)			
Interest and miscellaneous income	226,000	2,559,000	594,000
Interest and other expense	(1,385,000)	(1,281,000)	(1,278,000)
	(1,159,000)	1,278,000	(684,000)
Net loss	$ (10,238,000)	$ (6,935,000)	$ (9,384,000)
Basic and diluted loss per common share	$ (0.68)	$ (0.52)	$ (0.72)
Weighted average basic and diluted common shares outstanding	15,162,256	13,266,733	13,104,060
Net loss	$ (10,238,000)	$ (9,384,000)	$ (6,027,000)
Other comprehensive loss		-	-
Foreign currency translation adjustment	(17,000)	28,000	(14,000)
Comprehensive loss	$ (10,255,000)	$ (9,356,000)	$ (6,041,000)

</TABLE>

The accompanying notes are an integral part of these statements.

ACCESS PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

<TABLE>
<CAPTION>

	Common Stock		Additional paid-in	Notes receivable from	Unamortized value of restricted	Treasury	Accumulated other comprehensive income	Accumulated
	Shares	Amount	capital	stockholders	stock grants	stock	(loss)	deficit
<S>	<C>	<C>	<C>	<C>	<C>	<C>	<C>	<C>
Balance, January 1, 2002	12,909,000	$ 132,000	$ 48,057,000	$(1,045,000)	$ (154,000)	$ (4,000)	$ -	$(37,908,000)
Common stock for cash exercise of warrants and options	13,000	-	31,000	-	-	-	-	-
Common stock issued for cashless exercise of warrants	14,000	-	-	-	-	-	-	-
Common stock issued, purchase of assets	173,000	-	632,000	-	-	-	-	-
Warrants issued	-	-	80,000	-	-	-	-	-
Issuance of restricted stock grants	50,000	-	189,000	-	(190,000)	-	-	-
Other comprehensive loss	-	-	-	-	-	-	(14,000)	-
Amortization of restricted stock grants	-	-	-	-	67,000	-	-	-

Net loss	-	-	-	-	-	-	-	(9,384,000)
Balance, December 31, 2002	13,159,000	132,000	48,989,000	(1,045,000)	(277,000)	(4,000)	(14,000)	(47,292,000)
Common stock issued for cash exercise of warrants and options	103,000	1,000	266,000	-	-	-	-	-
Common stock issued for cashless exercise of warrants	80,000	1,000	(1,000)	-	-	-	-	-
Warrants issued	-	-	233,000	-	-	-	-	-
Issuance of restricted stock grants	55,000	-	110,000	-	(111,000)	-	-	-
Other comprehensive income	-	-	-	-	-	-	28,000	-
Amortization of restricted stock grants	-	-	-	-	94,000	-	-	-
Net loss	-	-	-	-	-	-	-	(6,935,000)
Balance, December 31, 2003	13,397,000	134,000	49,597,000	(1,045,000)	(294,000)	(4,000)	14,000	(54,227,000)
Common stock issued for cash, net of offering costs	1,789,000	18,000	8,998,000	-	-	-	-	-
Common stock issued for cash exercise of warrants and options	117,000	1,000	282,000	-	-	-	-	-
Common stock issued for cashless exercise of warrants	210,000	2,000	(2,000)	-	-	-	-	-
Issuance of restricted stock grants	12,000	-	135,000	-	(135,000)	-	-	-
Other comprehensive loss	-	-	-	-	-	-	(17,000)	-
Amortization of restricted stock grants	-	-	-	-	120,000	-	-	-
Net loss	-	-	-	-	-	-	-	(10,238,000)
Balance, December 31, 2004	15,525,000	$ 155,000	$ 59,010 000	$(1,045,000)	$ (309,000)	$ (4,000)	$ (3,000)	$(64,465,000)

</TABLE>

The accompanying notes are an integral part of these statements.

ACCESS PHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

<TABLE>
<CAPTION>

	Year ended December 31,		
	2004	2003	2002
<S>	<C>	<C>	<C>
Cash flows from operating activities:			
Net loss	$ (10,238,000)	$ (6,935,000)	$ (9,384,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Warrants issued in payment of consulting expenses	-	57,000	34,000
Impairment of investment	112,000	-	-
Amortization of restricted stock grants	120,000	94,000	67,000
Depreciation and amortization	773,000	621,000	439,000
Amortization of debt costs	183,000	183,000	183,000
Other long-term obligations	-	-	43,000
Change in operating assets and liabilities:			
Accounts receivable	358,000	47,000	(1,080,000)
Inventory	60,000	353,000	(461,000)
Prepaid expenses and other current assets	(195,000)	130,000	(241,000)
Other assets	(666,000)	(209,000)	130,000
Accounts payable and accrued expenses	401,000	(689,000)	983,000
Accrued interest payable	-	-	1,000

Deferred revenue	15,000	(15,000)	691,000
Net cash used in operating activities	(9,077,000)	(6,363,000)	(8,595,000)
Cash flows from investing activities:			
Capital expenditures	(221,000)	(336,000)	(403,000)
Redemptions of short-term investments and certificates of deposit, net	1,374,000	6,472,000	4,368,000
Purchase of businesses, net of cash acquired	-	-	(1,313,000)
Net cash provided by investing activities	1,153,000	6,136,000	2,652,000
Cash flows from financing activities:			
Payments of notes payable	(310,000)	(784,000)	(107,000)
Proceeds from stock issuances, net	9,299,000	266,000	32,000
Net cash provided by (used in) financing activities	8,989,000	(518,000)	(75,000)
Net increase (decrease) in cash and cash equivalents	1,065,000	(745,000)	(6,018,000)
Effect of exchange rate changes on cash and cash equivalents	(17,000)	28,000	36,000
Cash and cash equivalents at beginning of year	727,000	1,444,000	7,426,000
Cash and cash equivalents at end of year	$ 1,775,000	$ 727,000	$ 1,444,000
Cash paid for interest	$ 1,073,000	$ 1,281,000	$ 1,083,000
Cash paid for income taxes	-	-	-
Supplemental disclosure of noncash transactions			
Acquisitions of Australia patents			
Assets acquired	-	-	676,000
Stock and warrants issued	-	-	(676,000)
Value of restricted stock grants	135,000	111,000	190,000
Assets under capital lease capitalized during the year	59,000	126,000	-

</TABLE>

The accompanying notes are an integral part of these statements.

ACCESS PHARMACEUTICALS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
Three years ended December 31, 2004

NOTE 1 - NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

Access Pharmaceuticals, Inc. is a diversified emerging pharmaceutical company engaged in the development of novel therapeutics based primarily on the adaptation of existing therapeutic agents using its proprietary drug delivery platforms. Our efforts have been principally devoted to research and development, resulting in significant losses since inception on February 24, 1988. Prior to 2002, we presented our financial statements as a development stage enterprise.

A summary of the significant accounting policies applied in the preparation of the accompanying consolidated financial statements follows.

Principles of Consolidation

The consolidated financial statements include the financial statements of Access Pharmaceuticals, Inc. and our wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

We consider all highly liquid instruments with an original maturity of three months or less to be cash equivalents for purposes of the statements of cash flows. We invest our excess cash in government and corporate securities. Cash and cash equivalents consist primarily of cash in banks, money market funds and short-term corporate securities. All other investments are reported as short-term investments.

Short-term Investments

Short term investments consist of certificates of deposit. All short term investments are classified as held to maturity. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. The cost of securities sold is based on the specific identification method.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over estimated useful lives ranging from three to seven years.

Patents and Applications

We expense internal patent and application costs as incurred because, even though we believe the patents and underlying processes have continuing value, the amount of future benefits to be derived therefrom are uncertain. Purchased patents are capitalized and amortized over the life of the patent.

Licenses

We recognize the purchase cost of licenses and amortize them over their estimated useful lives.

Allowance for Doubtful Accounts

The Company estimates the collectibility of its trade accounts receivable. In order to assess the collectibility of these receivables, the Company monitors the current creditworthiness of each customer and analyzes the balances aged beyond the customer's credit terms. These evaluations may indicate a situation in which a certain customer cannot meet its financial obligations due to deterioration of its financial viability, credit ratings or bankruptcy. The allowance requirements are based on current facts and are reevaluated and adjusted as additional information is received. Trade accounts receivable are reserved when it is probable that the balance will not be collected.

NOTE 1 - NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - CONTINUED

Revenue Recognition

Licensing revenues are recognized over the period of our performance obligation. Licensing agreements generally require payments of fees on executing the agreement with milestone payments based on regulatory approvals and cumulative sales. Some agreements allow for the return of a portion of the initial execution fee if regulatory approvals are not received. In these cases the refundable balance is included as deferred revenue. Many of our agreements are for ten years with automatic extensions. Sponsored research and development revenues are recognized as research and development activities are performed under the terms of research contracts. Advance payments received are recorded as deferred revenue until the related research activities are performed. Royalty income is recognized as earned at the time the licensed product is sold. Option revenues are recognized when the earnings process is completed pursuant to the terms of the respective contract.

Revenue from product sales is recognized when the customer's order is shipped

from our third party logistics company's warehouse.

Research and Development Expenses

Pursuant to SFAS No. 2, "Accounting for Research and Development Costs," our research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, preclinical, development cost, clinical trial expense, outside manufacturing and consulting. The cost of materials and equipment or facilities that are acquired for research and development activities and that have alternative future uses are capitalized when acquired.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided for deferred tax assets to the extent their realization is in doubt

Loss Per Share

We have presented basic loss per share, computed on the basis of the weighted average number of common shares outstanding during the year, and diluted loss per share, computed on the basis of the weighted average number of common shares and all dilutive potential common shares outstanding during the year. Potential common shares result from stock options, convertible notes and warrants. However, for all years presented, all outstanding stock options, convertible notes and warrants are anti-dilutive.

Investment Securities

Investment securities consist of available for sale equity securities and short term investment are accounted for by the cost method. Available for sale securities are carried at fair value based on quoted market prices. Unrealized holding gains and losses, net of the related tax effect, on available for sale securities are excluded from earnings and are reported as a separate component of stockholders' equity until realized. Decline in the fair value of any available for sale security below cost that is determined to be other than temporary is charged to the statement of income. Realized gains and losses from the sale of available for sale securities are determined on average cost method and are included in earnings. Short-term investments consist of certificate of deposits, are held to maturity and are stated at cost.

Exchange Rate Translation

For international operations, local currencies have been determined to be the functional currencies. We translate assets and liabilities to their U.S. dollar equivalents at rates in effect at the balance sheet date and record translation adjustments in Shareholders' equity. We translate statement of income accounts at average rates for the period. Transaction adjustments are recorded in Other (income)/expense.

Restricted Cash

Restricted cash is cash that is or may be committed for a particular purpose. We have restricted cash for a deferred license agreement ($839,000), for a note payable ($233,000), and for rent guarantees for a manufacturing agreement and laboratory ($213,000).

NOTE 1 - NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - CONTINUED

Acquisition-Related Intangible Assets and Change In Accounting Principles

Effective January 1, 2002, we adopted SFAS 142, "Goodwill and Other Intangible Assets." Under SFAS 142, goodwill is no longer amortized but is subject to an impairment test at least annually or more frequently if impairment indicators arise. Separately identified and recognized intangible assets resulting from business combinations completed before July 1, 2001 that did not meet the new criteria for separate recognition of intangible assets were subsumed in goodwill upon adoption. The intangible assets of the company that did not meet the separate recognition criteria were licenses and acquired patents. We continue to amortize intangible assets that meet the new criteria over their useful lives. In accordance with SFAS 142, we performed a transitional impairment test of goodwill as of January 1, 2002, and an annual test in the fourth quarter of 2004, 2003 and 2002, which did not result in an impairment of goodwill.

Intangible assets consist of the following (in thousands):

<TABLE>
<CAPTION>

	December 31, 2004		December 31, 2003		December 31, 2002	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
<S>	<C>	<C>	<C>	<C>	<C>	<C>
Amortizable intangible assets						
Patents	$ 3,179	$ 864	$ 3,179	$ 527	$ 3,179	$ 188
Licenses	500	375	830	463	830	381
Total	$ 3,679	$ 1,239	$ 4,009	$ 990	$ 4,009	$ 569
Intangible assets not subject to amortization						
Goodwill	$ 2,464	$ 596	$ 2,464	$ 596	$ 2,464	$ 596

</TABLE>

The Company determined that one of its licenses was no longer useful for its current business focus and expensed $109,000 for the license net of amortization and royalty payable.

Amortization expense related to intangible assets totaled $420,000, $421,000 and $301,000 for the year ended December 31, 2004, 2003 and 2002, respectively. The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2004 is as follows (in thousands):

<TABLE>

<S>	<C>
2005	$ 388
2006	388
2007	363
2008	338
2009	338
Thereafter	625
Total	$ 2,440

</TABLE>

NOTE 1 - NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - CONTINUED

Stock-Based Compensation

We account for our stock option plan in accordance with the provisions of Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. Compensation expense is recorded only if the current market price of the underlying stock exceeds the exercise price on the date of grant. We have adopted the disclosure provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, which recognizes the fair value of all stock-based awards on the date of grant.

At December 31, 2004 we had two stock-based employee compensation plans, which are described more fully in Note 11. No stock-based employee compensation cost, other than compensation associated with options assumed in acquisitions, is reflected in net loss, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS 123, Accounting for Stock-Based Compensation, to stock-based employee compensation.

<TABLE>
<CAPTION>

	December 31,		
	2004	2003	2002
<S>	<C>	<C>	<C>
Net loss			
As reported	$(10,238,000)	$(6,935,000)	$ (9,384,000)
Pro forma stock option expense	(738,000)	(1,232,000)	(1,662,000)
Pro forma	(10,976,000)	(8,167,000)	(11,046,000)
Basic and diluted loss per share			
As reported	($ .68)	($ .52)	($ .72)
Pro forma stock option expense	(.05)	(.09)	(.12)
Pro forma	($ .73)	($ .61)	($ .84)

</TABLE>

The effect of our outstanding options and warrants are anti-dilutive when we have a net loss. The fully diluted shares are:

<TABLE>
<CAPTION>

	December 31,		
	2004	2003	2002
<S>	<C>	<C>	<C>
Fully diluted shares	20,567,301	18,837,344	18,786,202

</TABLE>

Stock compensation expense for options granted to nonemployees has been determined in accordance with SFAS 123 and EITF 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured.

Recent Accounting Pronouncement

On December 16, 2004, the FASB issued FAS 123R, "Share-Based Payment -- An Amendment of FASB Statements No. 123 and 95", (FAS 123R) which is effective for public companies in periods beginning after June 15, 2005. We will be required to implement the proposed standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a

modified prospective basis, would be measured and recognized on July 1, 2005. FAS 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise's equity instruments or that may be settled by the issuance of such equity instruments. FAS 123R would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require instead that such transactions be accounted for using a fair-value based method. Companies will be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans.

NOTE 1 - NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - CONTINUED

We are currently evaluating option valuation methodologies and assumptions of FAS 123R related to share based payments and the effect of adopting this pronouncement.

Use of Estimates

In preparing consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We tested goodwill for impairment based on estimates of fair value. It is at least reasonably possible that the estimates used by us will be materially different from actual amounts. These differences could result in the impairment of all or a portion of our goodwill, which could have a materially adverse effect on our results of operations.

Fair Value of Financial Instruments

The carrying value of cash, cash equivalents, short-term investments and certificates of deposit approximates fair value due to the short maturity of these items. It is not practical to estimate the fair value of the Company's long-term debt because quoted market prices do not exist and there were no available securities to use as a basis to value our debt.

NOTE 2 - LIQUIDITY

The Company incurred significant losses from operations of $9.1 million for the year ended December 31, 2004 and $8.2 million for the year ended December 31, 2003. Additionally, at December 31, 2004, we have a working capital deficit of $7,788,000. As of December 31, 2004, we did not have sufficient funds to repay our convertible notes at their maturity and support our working capital and operating requirements. As described below, in March 2005, we entered into financing arrangements we believe will allow us to meet our obligations under the convertible notes in the event we are unable to restructure or cause on terms acceptable to us.

As of March 30, 2005, the Company executed a Standby Equity Distribution Agreement (SEDA) with Cornell Capital Partners. Under the SEDA, the Company may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to $15,000,000. The purchase price for the shares is equal to their market price, which is defined in the SEDA as 98% of the lowest volume weighted average price of the common stock during a specified period of trading days following the date notice is given by the Company that it desires to access the SEDA. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the Equity Line of Credit. The amount of each draw down is subject to a maximum amount of $1,000,000. The terms of the SEDA do not allow us to make any draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our

outstanding shares of common stock. Based on the number of shares of our common stock currently outstanding, at volume weighted average price of $2.50, we could sell to Cornell Capital approximately $3,900,000 of our common stock subject to the 9.9% limitation. Thus, in order for the Company to receive all the funding available under the SEDA and have the financial resources it needs for operations and debt service, Cornell Capital must sell through to the market a significant portion of the shares it purchases under the arrangement. The Company believes that because the shares sold to Cornell Capital will be covered by an effective registration statement and Cornell Capital has a history of not holding significant positions in companies in which it invests, the shares purchased by Cornell Capital will be sold to the marketplace to maintain ownership below 9.9%. Provided that continuing sales to the marketplace are possible, the Company believes Cornell Capital will not accumulate 9.9% of the outstanding common stock of the Company; and, accordingly, the Company will be able to fully utilize the $15,000,000 made available through the SEDA.

Upon closing of the transaction, Cornell Capital Partners will receive a one-time commitment fee of 146,500 shares of the Company's common stock. On the same date, the Company entered into a placement agent agreement in escrow with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the placement agent agreement, upon closing of the transaction the Company will pay a one-time placement agent fee of 3,500 shares of common stock.

In addition, as of March 30, 2005, the Company executed a securities purchase agreement with Cornell Capital Partners and Highgate House Funds. Under the securities purchase agreement, upon closing Cornell Capital Partners and Highgate House Funds are obligated to purchase an aggregate of $2,633,000 principal amount of secured convertible debentures from the Company (net proceeds to the Company of $2,360,000). The secured convertible debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the secured convertible debenture has not been converted to common stock. The secured convertible debenture is convertible into the Company's common stock at the holder's option any time up to maturity at a conversion price equal to $4.00. The secured convertible debentures are secured by all of the assets of the Company. The Company has the right to redeem the secured convertible debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the securities purchase agreement, the Company is required to issue to the holders an aggregate of 50,000 shares of common stock of the Company.

The Company believes that based on the funds available from the agreements referred to above, as well as revenues from our operations, the Company will have the ability to pay its debt and other obligations as they come due.

NOTE 3 - ACQUISITIONS

Our wholly-owned subsidiary, Access Pharmaceuticals Australia Pty. Limited acquired the targeted therapeutic technology business of Biotech Australia Pty. Ltd under an Asset Sale Agreement dated February 26, 2002. Under the terms of the Asset Sale Agreement, Access Pharmaceuticals Australia Pty. Limited acquired the patents to three targeted therapeutics technologies and retained the scientific group that has developed this technology. The total consideration payable by us will be paid in a combination of cash and stock over a three-year period and is dependent on the achievement of certain technology milestones. We paid $500,000 at closing and an additional total of up to $525,000 will be paid over a three-year period. We also issued as consideration 172,584 shares of our common stock (valued at $633,000) and warrants to purchase 25,000 shares of our common stock at an exercise price of $5.00 per share (valued at $43,000 using the Black-Scholes option pricing model). The liability of $175,000 at December 31, 2004 was paid in 2005.

The three patented targeted therapeutic technologies acquired in this transaction are:

- folate conjugates of polymer therapeutics to enhance tumor delivery

by targeting folate receptors which are upregulated in certain tumor types;

- the use of vitamin B12 to target the transcobalamin II receptor which is upregulated in numerous diseases including cancer, rheumatoid arthritis and certain neurological and autoimmune disorders; and

- oral delivery of a wide variety of molecules, which cannot otherwise be orally administered, using the active transport mechanism which transports vitamin B12 into the systemic circulation.

The cost of the acquisition has been assigned principally to patents and will be amortized over the remaining useful life of the patents which averages ten years.

On July 22, 2002, we acquired from GlaxoSmithKline the patents, trademarks and technology covering the use of amlexanox for the treatment of mucosal and skin disorders. The two major components of the acquisition are the US marketing rights to amlexanox 5% paste which is currently marketed for the treatment of canker sores under the trademark Aphthasol(R), and the remaining worldwide marketing rights for this indication which were the subject of a prior licensing agreement between the companies. Under the terms of the agreement, we made an initial upfront payment of $750,000 and an additional payment of $250,000 on January 22, 2003.

NOTE 4 - RELATED PARTY TRANSACTIONS

Under a former consulting agreement between Thoma Corporation ("Thoma") and us, Thoma received payments for consulting services and reimbursement of direct expenses. Herbert H. McDade, Jr., our past Chairman of the Board of Directors, is an owner of Thoma Corp. Thoma received payments for consulting services and was also reimbursed for expenses as follows:

<TABLE>
<CAPTION>

Year	Consulting Fees	Expense Reimbursement
<S>	<C>	<C>
2002	$ 18,000	$ -

</TABLE>

NOTE 4 - RELATED PARTY TRANSACTIONS - CONTINUED

Stephen B. Howell, M.D., a Director, receives payments for consulting services and reimbursement of direct expenses and has also received warrants for his consulting services. Dr. Howell's payments for consulting services, expense reimbursements and warrants are as follows:

<TABLE>
<CAPTION>

Year	Consulting Fees	Expense Reimbursement	Warrants	Exercise Price	Fair Value
<S>	<C>	<C>	<C>	<C>	<C>
2004	$ 58,000	$ 9,000	-	$ -	$ -
2003	60,000	6,000	30,000	3.00	30,000
2002	55,000	3,000	10,000	4.91	37,000

</TABLE>

See Note 10 for a discussion of our Restricted Stock Purchase Program.

NOTE 5 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

<TABLE>
<CAPTION>

	December 31,	
	2004	2001
<S>	<C>	<C>
Laboratory equipment	$ 2,208,000	$ 1,972,000
Laboratory and building improvements	167,000	166,000
Furniture and equipment	204,000	196,000
	2,579,000	2,334,000
Less accumulated depreciation and amortization	1,539,000	1,330,000
Net property and equipment	$ 1,040,000	$ 1,004,000

</TABLE>

Depreciation and amortization on property and equipment was $244,000, $200,000, and $138,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

NOTE 6 - 401(k) PLAN

We have a tax-qualified employee savings and retirement plan (the "401(k) Plan") covering all our employees. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit ($13,000 in 2004; $12,000 in 2003; and $11,000 in 2002) and to have the amount of such reduction contributed to the 401(k) Plan. We have a 401(k) matching program whereby we contribute for each dollar a participant contributes a like amount, with a maximum contribution of 2% of a participant's earnings. The 401(k) Plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees or by us to the 401(k) Plan, and income earned on 401(k) Plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made. At the direction of each participant, we invest the assets of the 401(k) Plan in any of 23 investment options. Company contributions under the 401(k) Plan were approximately $46,000 in 2004; $45,000 in 2003; and $37,000 in 2002.

NOTE 7 - NOTE PAYABLE AND OTHER OBLIGATIONS

On September 20, 2001, we completed a $600,000 installment loan with a bank. The balance at December 31, 2004 is $233,000 and at December 31, 2003 was $354,000. The loan was used to purchase capital equipment and for leasehold improvements to expand our laboratory and office space. The loan is due in 60 equal installments, including interest at 6.5%. The loan is secured by a $233,000 certificate of deposit classified as an other asset at December 31, 2004.

On February 26, 2002, our wholly-owned subsidiary, Access Pharmaceuticals Australia Pty. Limited acquired the targeted therapeutic technology business of Biotech Australia Pty. Ltd under an Asset Sale Agreement. The last $175,000 payment was due and paid in the first quarter of 2005.

Future maturities of the note payable and other obligations are as follows:

<TABLE>
<CAPTION>

Future Maturities	Notes Payable and other obligations	Capital leases	Total
<S>	<C>	<C>	<C>
2005	$305,000	$ 82,000	$387,000

2006	103,000	36,000	139,000
Thereafter	53,000	-	54,000
	$461,000	$118,000	$580,000

</TABLE>

NOTE 8 - CONVERTIBLE NOTES

On September 20, 2000, we completed a $13.5 million convertible note offering. The offering was placed with three investors. Our convertible notes are due in two parts, $8,030,000 due on September 13, 2005 and $5,500,000 due on September 13, 2007. The notes bear interest at 7.7% per annum with $1,041,000 of interest due annually on September 13th. The notes have a fixed conversion price of $5.50 per share of common stock and may be converted by the note holder or us under certain circumstances as defined in the note. If the notes are not converted we will have to repay the notes on the due dates. Total expenses of issuance were $915,000 and are amortized over the life of the notes.

NOTE 9 - COMMITMENTS

At December 31, 2004, we have commitments under noncancelable operating leases for office and research and development facilities and equipment as follows:

<TABLE>
<CAPTION>

	Operating leases
<S>	<C>
2005	$ 305,000
2006	181,000
2007	140,000
2008	47,000
Total future minimum lease payments	$ 673,000

</TABLE>

Rent expense for the years ended December 31, 2004, 2003 and 2002 was $166,000, $165,000 and $138,000, respectively.

NOTE 10 - STOCKHOLDERS' EQUITY

Restricted Stock Purchase Program

On October 12, 2000, the Board of Directors authorized a Restricted Stock Purchase Program. Under the Program, the Company's executive officers and corporate secretary were given the opportunity to purchase shares of common stock in an individually designated amount per participant determined by the Compensation Committee of the Board of Directors. A total of 190,000 shares were purchased under the Program by four eligible participants at $5.50 per share, the fair market value of the common stock on October 12, 2000, for an aggregate consideration of $1,045,000. The purchase price was paid through the participant's delivery of a 50%-recourse promissory note payable to the Company for three executive officer participants and a full-recourse promissory note payable to the Company for the corporate secretary. Each note bears interest at 5.87% compounded semi-annually and has a maximum term of ten years. The notes are secured by a pledge of the purchased shares to the Company. The Company recorded the notes receivable from participants in this Program of $1,045,000 as a reduction of equity in the Consolidated Balance Sheet. Interest on the notes is neither being collected nor accrued.

The stock granted under the Program other than to the corporate secretary vested ratably over a four year period and is now fully vested. The stock

granted to the corporate secretary vested on the date of grant.

Warrants

There were warrants to purchase a total of 770,420 shares of common stock outstanding at December 31, 2004. All warrants were vested and exercisable at December 31, 2004. The warrants had various prices and terms as follows:

<TABLE>
<CAPTION>

Summary of Warrants	Warrants Outstanding	Exercise Price	Expiration Date
<S>	<C>	<C>	<C>
2004 offering (a)	447,344	$ 7.10	2/24/09
2004 offering (a)	156,481	5.40	2/24/09
2003 financial advisor (b)	72,000	3.90	10/30/08
2003 scientific consultant (c)	30,000	3.00	1/1/06
2002 warrants offered in acquisition (d)	25,000	5.00	2/26/05
2002 scientific consultant (e)	10,000	4.96	2/01/09
2001 scientific consultant (f)	15,000	3.00	1/1/08
2000 offering (g)	14,595	2.50	3/01/05
Total	770,420		

</TABLE>

a) In connection with offering of common stock in 2004, warrants to purchase a total of 603,825 shares of common stock were issued. All of the warrants are exercisable immediately and expire five years from date of issuance.

b) During 2003, financial advisors received warrants to purchase 72,000 shares of common stock at any time from October 30, 2003 until October 30, 2008, for financial consulting services rendered in 2003 and 2004. All the warrants are exercisable. The fair value of the warrants was $2.82 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.9%, expected volatility 92% and a term of 5 years.

NOTE 10 - STOCKHOLDERS' EQUITY - CONTINUED

c) During 2003, a director who is also a scientific advisor received warrants to purchase 30,000 shares of common stock at an exercise price of $3.00 per share at any time from January 1, 2003 until January 1, 2006, for scientific consulting services rendered in 2003. The fair value of the warrants was $.99 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.26%, expected volatility 98% and a term of 3 years.

d) During 2002, a company received warrants to purchase 25,000 shares of common stock at an exercise price of $5.00 per share at any time from February 26, 2002 until February 26, 2005. The warrants were issued in connection with the acquisition of patents in Australia. The fair value of the warrants was $1.72 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.67%, expected volatility 81% and a term of 3 years. The warrants expired on February 26, 2005 without being exercised.

e) During 2002, a director who is also a scientific advisor received warrants to purchase 10,000 shares of common stock at an exercise price of $4.91 per share at any time from February 1, 2002 until February 1, 2009, for scientific consulting services rendered in 2002. The fair value of the warrants was $3.70 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free

interest rate 3.90%, expected volatility 81% and a term of 7 years.

f) During 2001, a director who is also a scientific advisor received warrants to purchase 15,000 shares of common stock at an exercise price of $3.00 per share at any time from January 1, 2001 until January 1, 2008, for scientific consulting services rendered in 2001. The fair value of the warrants was $2.74 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 5.03%, expected volatility 118% and a term of 7 years.

g) In connection with offerings of common stock in 2000, warrants to purchase a total of 509,097 shares of common stock were issued. All of the warrants are exercisable immediately and expire five years from date of issuance.

2001 Restricted Stock Plan

We have a restricted stock plan, the 2001 Restricted Stock Plan, under which 200,000 shares of our authorized but unissued common stock were reserved for issuance to certain employees, directors, consultants and advisors. The restricted stock granted under the plan generally vests over five years, 25% two years after the grant date with additional 25% vesting every anniversary date. All stock is vested after five years. At December 31, 2004 there were 161,238 shares granted and 38,762 shares available for grant under the 2001 Restricted Stock Plan.

NOTE 11 - STOCK OPTION PLANS

We have a stock option plan, as amended, (the "1995 Stock Awards Plan"), under which 2,500,000 shares of our authorized but unissued common stock were reserved for issuance to optionees including officers, employees, and other individuals performing services for us. The 1995 Stock Awards Plan replaced the previously approved stock option plan (the "1987 Stock Awards Plan"). On February 11, 2000 we adopted the 2000 Special Stock Option Plan and Agreement (the "Plan"). The Plan provides for the award of options to purchase 500,000 shares of the authorized but unissued shares of common stock of the Company. Options granted under all the plans generally vest ratably over a four to five year period and are generally exercisable over a ten-year period from the date of grant. Stock options are generally granted with an exercise price equal to the market value at the date of grant.

At December 31, 2004, there were 129,780 additional shares available for grant under the 1995 Stock Awards Plan.

The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in fiscal 2004, 2003 and 2002, respectively: dividend yield of 0% for all periods; volatility of 41%, 117% and 98%; risk-free interest rates of 3.61%, 2.26% and 2.03%, respectively, and expected lives of four years for all periods. The weighted average fair values of options granted were $2.18, $1.56 and $2.46 per share during 2004, 2003 and 2002, respectively.

Summarized information for the 1995 Stock Awards Plan is as follows:

<TABLE>
<CAPTION>

	Shares	Weighted-average exercise price
<S>	<C>	<C>
Outstanding options at January 1, 2002	1,280,584	$ 3.68
Granted, fair value of $2.46 per share	493,000	3.53

Exercised	(2,428)	2.08
Forfeited	(60,000)	3.17
Outstanding options at December 31, 2002	1,711,156	3.59
Granted, fair value of $1.56 per share	374,500	2.20
Exercised	(28,000)	2.55
Forfeited	(4,000)	2.70
Outstanding options at December 31, 2003	2,053,656	3.45
Granted, fair value of $2.18 per share	314,200	5.75
Exercised	(109,695)	2.38
Forfeited	(75,980)	4.21
Outstanding options at December 31, 2004	2,182,181	3.76
Exercisable at December 31, 2002	997,570	3.35
Exercisable at December 31, 2003	1,389,185	3.49
Exercisable at December 31, 2004	1,671,160	3.64

</TABLE>

NOTE 11 - STOCK OPTION PLANS - CONTINUED

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2004 is summarized below:

<TABLE>
<CAPTION>

	Number of shares	Weighted average Remaining	Exercise	Number of shares	Weighted-average exercise
Range of exercise prices	outstanding	life in years	price	exercisable	price
<S>	<C>	<C>	<C>	<C>	
$2.00-2.18	417,063	6.5	$ 2.01	333,436	$ 2.01
$2.30-2.81	352,100	7.8	2.44	275,183	2.47
$2.94-3.99	716,318	6.4	3.43	585,104	3.36
$4.05-7.8125	696,700	7.7	5.82	477,437	5.80
	2,182,181			1,671,160	

</TABLE>

Under the 2000 Special Stock Option Plan, 500,000 options were issued in 2000 and are outstanding at December 31, 2004. All of the options in the 2000 Special Stock Option Plan were exercisable at December 31, 2004, 468,749 of the options were exercisable at December 31, 2003 and 343,749 of the options were exercisable at December 31, 2002. All of the options expire on March 1, 2010 and have an exercise price of $2.50 per share.

All issued options under the 1987 Stock Awards Plan expired in 2004. No further grants can be made. Summarized information for the 1987 Stock Awards Plan is as follows:

<TABLE>
<CAPTION>

	Stock options	Weighted-average exercise price
<S>	<C>	<C>
Outstanding awards at January 1, 2002	26,002	$ 46.18
Forfeited	(8,824)	90.45

Outstanding awards at December 31, 2002	17,178	23.31
Forfeited	(5,750)	35.00
Outstanding awards at December 31, 2003	11,428	17.42
Forfeited	(11,428)	17.42
Outstanding awards at December 31, 2004	-	

</TABLE>

NOTE 12 - INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

<TABLE>
<CAPTION>

	2004	2003	2002
<S>	<C>	<C>	<C>
Income taxes at U.S. statutory rate	$ (3,442,000)	$ (2,358,000)	$ (3,191,000)
Change in valuation allowance	1,493,000	(111,000)	1,153,000
Expenses not deductible	7,000	40,000	15,000
Expiration of net operating loss and general business credit carryforwards, net of revisions	1,942,000	2,429,000	2,023,000
Total tax expense	$ -	$ -	$ -

</TABLE>

Deferred taxes are provided for the temporary differences between the financial reporting bases and the tax bases of our assets and liabilities. The temporary differences that give rise to deferred tax assets were as follows:

<TABLE>
<CAPTION>

	December 31,		
	2004	2003	2002
<S>	<C>	<C>	<C>
Deferred tax assets (liabilities)			
Net operating loss carryforwards	$ 20,808,000	$ 20,193,000	$ 20,487,000
General business credit carryforwards	2,094,000	1,960,000	1,356,000
Property, equipment and goodwill	259,000	113,000	119,000
Gross deferred tax assets	23,161,000	22,266,000	21,962,000
Valuation allowance	(23,161,000)	(22,266,000)	(21,962,000)
Net deferred taxes	$ -	$ -	$ -

</TABLE>

At December 31, 2004, we had approximately $55,488,000 of net operating loss carryforwards and approximately $2,094,000 of general business credit carryforwards. These carryforwards expire as follows:

<TABLE>
<CAPTION>

	Net operating loss carryforwards	General business credit carryforwards

2005	$ 3,014,000	$ 26,000
2006	587,000	38,000
2007	994,000	26,000
2008	4,004,000	138,000
2009	1,661,000	185,000
Thereafter	45,228,000	1,680,000
	$ 55,488,000	$ 2,094,000

As a result of a merger on January 25, 1996, a change in control occurred for federal income tax purposes which limits the utilization of pre-merger net operating loss carryforwards of approximately $3,100,000 to approximately $530,000 per year.

NOTE 13 - SETTLEMENT WITH BLOCK DRUG COMPANY

On July 22, 2002 we entered into a Supply Agreement whereby Block Drug Company (Block) was required to produce Aphthasol(R) for us for a defined period of time at its Puerto Rico facility. Subsequently we were advised by Block that it was unable to produce Aphthasol(R) for us pursuant to the Supply Agreement. In May 2003, we reached a settlement with Block relating to this matter whereby Block made a one-time cash payment to us, we recorded $2,280,000 in Miscellaneous Income and Block was relieved of its obligations under the Supply Agreement and the Asset Sale Agreement, pursuant to which we had purchased certain assets relating to amlexanox and Aphthasol(R) from Block, and we were relieved from certain future obligations under the Asset Sale Agreement.

NOTE 14 - QUARTERLY FINANCIAL DATA (UNAUDITED)

Our results of operations by quarter for the years ended December 31, 2004 and 2003 were as follows (in thousands, except per share amounts):

	2004 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue	$ 20	$ 68	$ 185	$ 276
Operating loss	(2,064)	(2,176)	(2,229)	(2,610)
Net loss	$ (2,351)	$ (2,553)	$ (2,428)	$ (2,906)
Basic and diluted loss per common share	$ (0.17)	$ (0.17)	$ (0.16)	$ (0.18)

	2003 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue	$ 393	$ 683	$ 11	$ 208
Operating loss	(2,194)	(1,694)	(1,943)	(2,382)
Net income (loss)	$ (2,411)	$ 316	$ (2,206)	$ (2,634)
Basic and diluted income (loss) per common share	$ (0.18)	$ 0.02	$ (0.17)	$ (0.19)

EXHIBIT 21

SUBSIDIARIES OF THE REGISTRANT

Access Pharmaceuticals Australia Pty. Limited, a New South Wales, Australia company

Tacora Corporation, a Delaware company

Virologix Corporation, a Delaware company

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our reports dated March 31, 2005, accompanying the consolidated financial statements and management's assessment of the effectiveness of internal control over financial reporting included in the Annual Report of Access Pharmaceuticals, Inc. on Form 10-K for the year ended December 31, 2004. We hereby consent to the incorporation by reference of said reports in the Registration Statements of Access Pharmaceuticals, Inc. on Forms S-3 (File Nos. 333-92210, 333-39330, 333-37786, File No. 333-52030, File No. 333-95413 and File Nos. 333-64904) and on Forms S-8 (File No. 33-10626, File No. 33-41134, File No. 333-45646 and 333-75136).

/s/ Grant Thornton LLP

Dallas, Texas
March 31, 2005

EXHIBIT 31.01

CHIEF EXECUTIVE OFFICER CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kerry P. Gray, the Chief Executive Officer of Access Pharmaceuticals, Inc., certify that:

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

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

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

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

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

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

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

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

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

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Dated: March 31, 2005 /s/ Kerry P. Gray

Kerry P. Gray
President and Chief Executive Officer

EXHIBIT 31.02

CHIEF FINANCIAL OFFICER CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen B. Thompson, the Chief Financial Officer of Access Pharmaceuticals, Inc., certify that:

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

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

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

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

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

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

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

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

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

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

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

Dated: March 31, 2005 /s/ Stephen B. Thompson

Stephen B. Thompson
Chief Financial Officer

EXHIBIT 32.01

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

This certification set forth below is hereby made solely for the purposes of satisfying the requirements of Section 906 of the Sarbanes-Oxley Act of 2002 and may not be relied upon or used for any other purposes.

A signed original of this written statement required by Section 906 has been provided to Access Pharmaceuticals, Inc. and will be retained by Access Pharmaceuticals, Inc. and furnished to the SEC or its staff upon its request.

Pursuant to Section 906 of the Public Company Accounting Reform and Investor Act of 2002 (18 U.S.C. 1350, as adopted, the "Sarbanes-Oxley Act"), Kerry P. Gray, President and Chief Executive Officer of Access Pharmaceuticals, Inc. (the "Company"), and Stephen B. Thompson, Vice President and Chief Financial Officer of the Company, each hereby certifies that to his knowledge the Annual Report on Form 10-K for the period ended December 31, 2004 of the Company filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period specified.

Signed at the City of Dallas, in the State of Texas, this 31st day of March, 2005.

/s/ Kerry P. Gray	/s/ Stephen B. Thompson
- ----------	----------
Kerry P. Gray	Stephen B. Thompson
President and Chief Executive Officer	Chief Financial Officer