

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

FORM 10-K

Annual Report pursuant to Section 13 or 15(d) of the Securities  
Exchange Act of 1934 for the fiscal year ended December 31, 2001  
or  
 Transition Report pursuant to Section 13 or 15 (d) of the Securities  
Exchange Act of 1934 for the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 0-9314

ACCESS PHARMACEUTICALS, INC.

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(Exact name of registrant as specified in its charter)

Delaware	83-0221517
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(State of Incorporation)	(I.R.S. Employer I.D. No.)
2600 Stemmons Freeway, Suite 176, Dallas, TX	75207
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(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

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(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  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. \_\_\_\_\_

The aggregate market value of the outstanding voting stock held by non-  
affiliates of the registrant as of March 28, 2002 was approximately  
\$40,431,000.

As of March 28, 2002 there were 13,051,734 shares of Access Pharmaceuticals,  
Inc. Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: Portions of Registrant's Definitive  
Proxy Statement filed with the Commission pursuant to Regulation 14A in  
connection with the 2002 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.

PART I

ITEM 1. BUSINESS

Business

Access Pharmaceuticals is a Delaware corporation in the development

stage. 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 have proprietary patents or rights to seven drug delivery technology platforms: synthetic polymer targeted delivery, vitamin mediated targeted delivery (including oral), bioerodible hydrogel technology, nanoparticles and nanoparticle networks, Residerm (R) topical delivery, carbohydrate targeting technology and agents for the prevention and treatment of viral disease, including HIV.

We use our proprietary technology to develop products and product candidates, including our marketed products, amlexanox 5% paste (marketed under the trade names Aphthasol (R) and Apthéal (R)) and Zindaclin (TM), and our products that are currently in development status, polymer platinat (AP 5280), DACH platinum, OraDisc (TM), OraRinse (TM), amlexanox cream, amlexanox gel, and mucoadhesive liquid technology.

We jointly developed amlexanox 5% paste, the first U.S. Food and Drug Administration, or FDA, approved product for the treatment of canker sores, with our partner GlaxoSmithKline, formerly Block Drug Company. GlaxoSmithKline is marketing this product under the trade name Aphthasol (R) in the United States and in September 2001, another of our partners, Strakan Limited, received marketing authorization to market amlexanox 5% paste in the United Kingdom under the trade name Apthéal (R). We have licensed certain rights for the use of amlexanox in additional indications from GlaxoSmithKline for numerous markets, including the worldwide rights for mucositis and for other products, excluding the U.S. We are developing new formulations and delivery forms of amlexanox for use in additional clinical indications, including mucoadhesive disc delivery and mucoadhesive liquid delivery.

In addition, Strakan has used our patented Residerm (R) technology to develop zinc clindamycin for the treatment of acne. Strakan began marketing zinc clindamycin in the United Kingdom under the trade name Zindaclin (TM) in March 2002. The process to achieve marketing authorization for Zindaclin (TM) throughout Europe has been initiated and we expect the first country approvals by the end of 2002.

#### Recent Developments

In February 2002, our newly created wholly owned subsidiary, Access Pharmaceuticals Australia Pty. Limited acquired the targeted therapeutic technology business of Biotech Australia Pty. Ltd.

Under the terms of the acquisition 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. The stock consideration to be paid is subject to restriction and cannot be sold until February 27, 2003.

The three patented targeted therapeutic technologies acquired 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 inventor of these technologies, Dr. Gregory Russell-Jones, joined our scientific team as Vice President of Targeted Therapeutics. In addition, we acquired an internal capability to perform biological studies which we previously out-sourced. We expect that this capability will enhance our ability to identify lead compounds more rapidly and develop the necessary preclinical data for regulatory filings. This acquisition is a step towards the achievement of the critical mass necessary for us to accelerate the

development of our technology platforms.

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In March 2002, we announced positive results of two preclinical studies of our mucoadhesive liquid delivery technology for the prevention and treatment of oral mucositis and our plan to advance this technology to a pivotal clinical study. Following the completion of our Phase II study in 2001 in patients undergoing radiation therapy with or without concomitant chemotherapy for the treatment of head and neck cancer, we decided to conduct additional formulation development work to optimize the technology prior to advancing clinical development. The topical application of the mucoadhesive liquid delivery technology was tested for its ability to attenuate the course of radiation-induced oral mucositis in an established hamster model. A single dose of radiation was administered to the hamster which consistently produces clinically significant ulcerative mucositis similar to that observed in humans (NCI-CTC score of 3 or 4). The severity of the mucositis is graded on a scale of 0-5 with 1 representing erythema, 3 being formation of ulcers in one or more places and 5 indicating ulceration of virtually the entire area. The study results clearly indicate the ability to prevent the onset of ulcerative mucositis, delay the onset and reduce the severity of mucositis. Specifically, treatment with the optimal formulation resulted in the following:

- \* 29% of the animals did not register a score above 1 for the duration of the study;
- \* 43% of the animals did not register a score of above 2 compared to 100% of the animals treated with saline reporting scores of 3 and above; and
- \* compared to animals treated with saline there was a 65% reduction in the number of days when animals presented with ulcerative mucositis.

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 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 currently is the only compound approved by the FDA for the treatment of canker sores. Independent market research sponsored by us indicates that more than 7 million patients visit doctors or 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, of which 15 million patients claim that their canker sores recur.

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.

In 1995, we sold our rights to amlexanox to Block, subject to a retained royalty. On June 8, 1998, we entered into an agreement to license these rights back from Block for certain international markets and indications. Pursuant to this agreement, 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 Strakan in August 1998. Under the terms of this license, Strakan is responsible for and will bear all costs associated with the regulatory approval process, including product registration, for amlexanox in the United Kingdom and the European Union. Additionally, Strakan will make milestone payments to us on achievement of performance objectives and we will receive royalties on product sales of amlexanox.

Strakan, received marketing authorization for amlexanox 5% paste in the United Kingdom in September 2001. Strakan's trade name for the product is Aptheal (R). We anticipate that the amlexanox 5% paste product will be registered throughout Europe during the year 2002.

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An international outlicensing program for amlexanox is ongoing. In addition to our license agreement with Strakan, licensing agreements have been executed with Meda AB for Scandinavia, the Baltic states and Iceland; Laboratorios Esteve for Spain, Portugal and Greece; Mipharm S.p.A. for Italy, Switzerland, Turkey and Lebanon; and Paladin Labs Inc. for Canada.

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.

### Residerm (R) A gel - Zindaclin (TM) (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).

The first zinc drug complex that we have developed, in conjunction with Strakan, is zinc clindamycin for the treatment of acne which is marketed under the trade name Zindaclin (TM). 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 (TM) 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 Strakan. Under the terms of the license agreement, Strakan 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. The license agreement also provides that Strakan will make milestone payments to us on achievement of commercial objectives and that we will receive royalties on sales of products based on our Residerm (R) topical delivery technology.

Strakan currently is marketing zinc clindamycin in the United Kingdom under the trade name Zindaclin (TM). The process to achieve marketing authorization for Zindaclin (TM) throughout Europe has been initiated and we expect the first country approvals by the end of 2002. In addition, in March 2001 Strakan signed an Option and License Agreement with Healthpoint, Ltd., which granted a license to Healthpoint for rights to both Residerm (R) A and our Residerm (R) topical delivery technology for the U.S., Canada, Mexico and the Caribbean.

### Products in Development Status

#### Polymer Platinate (AP 5280)

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, neuropathy, or irreversible cardiotoxicity, is another limitation of current anti-cancer drugs that can prevent their administration in curative doses.

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Currently, platinum compounds are one of the largest selling categories of chemotherapeutic agents, with annual sales in excess of \$800 million. 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.

AP5280 is a chemotherapeutic agent that we believe has the potential to have significantly superior effectiveness in treating numerous cancers compared to platinum compounds currently in use. Our patented AP5280 product seeks to achieve this goal by attaching a large polymer to a small platinum molecule. This method exploits the usually leaky or hyperpermeable, nature of the cells that line the walls of blood vessels that feed tumors by allowing the large AP5280 molecule to enter the tumor in preference to other tissue, which do not have leaky or hyperpermeable blood vessels. In addition, the capillary/lymphatic drainage system of tumors is not well developed and limited, so the drug gets trapped in the tumor. This dual effect is called enhanced permeability and retention, or EPR. In addition, the polymer is designed to shield the platinum from interactions with normal cells while the drug circulates within the body, thereby reducing toxicity. The proposed mechanism of how AP5280 is taken up by tumor cells bypasses known membrane-associated mechanisms for development of tumor resistance, a common cause of failure of chemotherapeutic drugs over the course of treatment.

In animal models, our AP5280 compounds have delivered up to 70 times the amount of platinum to tumors compared with cisplatin, the standard platinum formulation, at the maximum tolerated dose. AP5280 was approximately as effective in inhibiting tumor growth as cisplatin alone at doses up to 10 times less toxic. In terms of dosing, in animal studies, up to 70 times more platinum has been injected using our AP5280, which could be clinically significant as platinum has a steep dose response curve. Consequently, clinical outcome could be greatly improved as a result of the ability to deliver additional amounts of the drug to the tumor. In addition, the anti-tumor effect of platinum drugs is generated by the platinum binding to the DNA, which initiates the process of tumor cell death. In a B16 melanoma rodent model, it was demonstrated that AP5280 formed at least 11 times more platinum DNA complexes in tumors than did Carboplatin, the market leading platinum drug, when both agents were administered intravenously at doses which generated equal toxicity.

We have developed the AP5280 clinical formulation, defined the manufacturing and analytical methods for AP5280 and produced material for clinical trials. We commenced Phase I human clinical trials for AP5280 in September 2000 and estimate completion of the trial in the second quarter of 2002. The initial Phase I study protocol is designed to determine the maximum tolerated dose of AP5280, where the dose-limiting toxicity is identified using the standard once every three weeks platinum dosing regimen. This study is being conducted at two European

sites.

#### DACH Platinum

The extensive experience we have gained developing AP5280 has been applied to extend the 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 generating sales in excess of \$150 million annually. Carboplatin and Cisplatin, the most widely prescribed drugs, are not indicated for the treatment of metastatic colorectal cancer. Oxaliplatin, in combination with 5-fluorouracil and folinic acid is indicated for the first-line treatment of metastatic colorectal cancer in Europe. 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.

In May 2001 we announced the expansion of our polymer platinate activities to include a development program for the prodrug of oxaliplatin, AP5286. A number of formulations have been developed, and initial in vitro, acute toxicity and efficacy data has been generated. We believe that this initial data is encouraging and we have developed several additional formulations with the objective of maximizing the therapeutic benefit of the clinical development candidate. The lead development candidate has been chosen and we plan to complete the necessary preclinical development package in 2002 and commence clinical studies.

#### OraDisc (TM) (Amlexanox)

We are working to develop a mucoadhesive disc that adheres to canker sores and slowly erodes over time locally releasing amlexanox at the site of the canker sore.

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This OraDisc (TM) formulation is an improved delivery vehicle for the oral delivery of amlexanox which potentially overcomes the difficulties encountered in using conventional paste and gel formulations for conditions in the mouth, that is, applying the drug and keeping it in place over time. Utilizing this technology, we anticipate that higher drug concentrations will be achieved at the disease site increasing the effectiveness of the product.

A Phase I tolerance study to evaluate skin irritation of this formulation was successfully completed in 1999 and a pilot Phase II study evaluating the oral wound healing capacity of OraDisc (TM) was completed in January 2000 with both studies generating positive results.

An Investigational New Drug Application, or IND, was filed with the FDA in April 2000 and a 400 patient placebo-controlled multi-center study evaluating OraDisc (TM) for the treatment of established canker sores was completed in December 2000. In the study, three groups were evaluated; approximately 160 patients were treated with active OraDisc (TM), while 160 patients received a placebo disc and 80 patients received no treatment. The primary clinical endpoint which evaluated complete healing on day 5 was achieved, with accelerated healing with OraDisc (TM) being statistically significant, compared with both the placebo and no treatment groups.

A second Phase III study evaluating OraDisc (TM) for the treatment of established canker sores is scheduled to begin in the second quarter 2002. On completion of this study we plan to submit a new drug application to the FDA.

#### OraRinse (TM) and Mucoadhesive Liquid Technology

In 1998 we executed a license agreement with Block Drug Company, now GlaxoSmithKline, for the rights to develop amlexanox for use in chemotherapy and radiation induced mucositis. 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. The potential worldwide market size for products to treat mucositis is estimated to be in excess of \$1.5 billion.

We filed an IND with the FDA in December 1999 and developed a Phase II protocol to investigate a mouthwash formulation, OraRinse (TM), 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 OraRinse (TM) for the prevention and treatment of mucositis. The data developed confirms that the mucoadhesive liquid technology could be a platform technology and appears to represent an important advancement in the management and prevention of mucositis.

The data has been 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 mucoadhesive liquid technology, and the fact that in the study amlexanox 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 technology prior to advancing clinical development. The topical application of the mucoadhesive technology 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, delay the onset and reduce the severity of mucositis. We have met with the FDA to determine

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the most expeditious way to advance our mucositis clinical development program. Prior to finalizing the pivotal clinical study protocol, the primary clinical endpoint has to be agreed with the FDA.

We are, however, evaluating the possibility of developing a range of products utilizing our mucoadhesive liquid technology for the management of the various phases of the disease. In addition to our prevention product candidate, we are exploring the incorporation of an analgesic for pain management or compounds for the treatment of bacterial or fungal infections into our mucoadhesive liquid technology.

We are currently planning a Phase III clinical trial for the third quarter of 2002.

#### Amlexanox Cream and Gel

Clinical studies evaluating the cream and gel formulations of amlexanox were conducted in 2001. The results achieved indicate that additional formulation development and preclinical testing will be required prior to the advancement of clinical development.

Prior to committing to further advancing this program an assessment of the costs to be incurred for development, the development timeline, the development risks and the profile of competitive products will be conducted. In addition, the potential returns that could be achieved

investing in alternative programs will be considered prior to deciding on whether to proceed further with these developments.

#### Viral Disease Technology

We acquired our viral disease technology through our acquisition of Virologix. This technology is targeted for the prevention and treatment of viral diseases, including HIV. These compounds target a critical enzyme involved in viral infection and replication. Analogous to reverse transcriptase and protease inhibitors that have shown effectiveness against HIV. A Phase I/II study will be designed to study this product candidate in HIV patients. Positive clinical data would provide important validation for this new class of HIV therapeutics. We also have technology for treating HTLV type I and II infection. We acquired a part of this technology through a licensing agreement with the National Institute of Health.

#### 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 The University of Kentucky for the formulation of an amlexanox gel, Strakan for the delivery of topical therapeutic agents which exploit our zinc patent, the University of Missouri for formulation research and the University of North Texas for nanoparticles and nanoparticle network technology. Additionally, our polymer platinate technology has 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, preclinical testing and product production to research organizations, contract manufacturers and strategic partners. 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.

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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 criterion 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 that we are using to selectively deliver drugs to target sites for use in cancer chemotherapy, dermatology and oral disease are:

- \* Synthetic Polymer Targeted Drug Delivery Technology;
- \* Vitamin Mediated Targeted Delivery Technology;
- \* Bioerodeable Hydrogel Delivery Technology;
- \* Nanoparticle Network Delivery Technology;
- \* Residerm (R) Topical Delivery Technology; and
- \* Carbohydrate Targeting Drug Delivery Technology

We also are developing agents for the prevention and treatment of viral disease. 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 platinate, designed to exploit enhanced permeability and retention, or EPR, at tumor sites to selectively accumulate drug and control drug release. Many solid tumor cells 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 trapped in 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

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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 more localized effect where it is needed. Our 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.

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 or specific genes 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. The 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 or gene 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.

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 which involve attaching the protein or peptide to a molecule which 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 which 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 the 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 which 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 which VB12 is also attached. For drugs which are unstable in the stomach, but stable in the intestinal tract, the VB12 conjugate can be incorporated in an enteric coated capsule. A further option, especially for drugs and macromolecules which 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.

#### Bioerodeable Hydrogel Delivery Technology

Our bioerodeable hydrogel technology is one of our priority internal development focuses. Our scientists have developed a novel series of bioerodeable hydrogels which have the potential to be utilized 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 bioerodeable, 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 bioerodeable 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 can be developed using the Access bioerodible hydrogel 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 filed a U.S. patent application relating to our bioerodible hydrogel technology.

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We have filed patent applications for our bioerodeable hydrogel technology, which is one of our priority internal development focuses. Our bioerodeable hydrogel technology has the following properties:

- \* contains a network polymer that swells in water;
- \* it has cleavable bonds in a linear polymer backbone;
- \* breakdown occurs in a biological or aqueous environment;
- \* controlled degradation rates ranging from hours to months can be achieved; and
- \* offers the ability to control drug incorporation and release by the choice of polymer, crosslink density and link degradation rate.

#### Nanoparticle Network Delivery Technology

Our nanoparticles network delivery system involves first producing hydrogel nanoparticles and then bonding them together resulting in a new class of gels with two levels of engineered structural difference: the primary network and the secondary network. The primary network is crosslinked polymer chains inside each nanoparticle, while the secondary network is a crosslinked system of the nanoparticles themselves. As a result, the nanoparticle network could be used to entrap and deliver small and/or very large biomolecules or other active compounds with its primary and secondary structures, respectively. These unique properties will enhance the versatility of polymer gel nanoparticle networks as potential carriers to provide controlled delivery of a variety of active compounds.

In addition, such nanostructured gels have new and novel properties that conventional gels do not possess. These properties include a high surface area, a unique and distinguishable color at room temperature, and the ability to be easily combined together if desired to yield heterogeneous networks consisting of diversified physical and chemical properties. Our research and development efforts may lead to creating opportunities in a variety of technological applications, including controlled delivery of drugs or other actives, optical and colorimetric sensors, interferometer systems, holographic or interference gratings, integrated circuit lithography, optical displays, environmental cleanup agents and bio-adhesives.

#### Residerm (R) Topical Delivery Technology

We have granted a license to Strakan 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 which 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,

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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.

#### Carbohydrate Targeting Drug Delivery Technology

Our carbohydrate polymer drug delivery technology exploits specific changes in the vascular endothelium that occur during disease processes. These carriers mimic disease-specific, carbohydrate recognition by vascular endothelium cells and underlying tissue. It has been well established that white blood cells can recognize, target and permeate disease sites by means of surface carbohydrates which bind to cytokine-induced endothelium plus underlying tissue and cells. A number of receptors on the endothelium and on underlying tissue are known to bind sulfated glycosaminoglycans, such as heparin and dermatan sulfate. We have developed glycosaminoglycan carriers to selectively image and treat diseases involving the neovascular endothelium. We believe that our glycosaminoglycan technology has broad potential in a number of therapeutic applications including cancer, inflammation and infection.

#### Viral Disease Technology

We acquired our viral disease technology through our acquisition of Virologix. This technology is targeted for the prevention and treatment of viral diseases, including HIV. These compounds target a critical enzyme involved in viral infection and replication. Analogous to reverse transcriptase and protease inhibitors that have shown effectiveness against HIV. A Phase I/II study will be designed to study this product candidate in HIV patients. Positive clinical data would provide important validation for this new class of HIV therapeutics. We also have technology for treating HTLV type I and II infection. We acquired a part of this technology through a licensing agreement with the National Institute of Health.

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#### Research Projects, Products and Products in Development

<TABLE>  
<CAPTION>

##### ACCESS DRUG PORTFOLIO

##### Clinical

Compound	Originator	Indication	FDA Filing	Stage (1)
<S>	<C>	<C>	<C>	<C>
Cancer				
Polymer Platinate (AP5280) (2)	Access	Anti-tumor	Development	Phase I
Polymer Platinate (AP5286) (2)	Access	Colorectal Cancer	Development	Pre-Clinical
OraRinse (TM)	Access	Mucositis	IND	Phase III
Topical Delivery				
Amlexanox (3)	Takeda	Oral ulcers	NDA	Approved

OraDisc (TM) Amlexanox (3)					
Biodegradable Polymer Disc	Takeda	Oral ulcers	IND	Phase III	
Residerm (R) A					
Zinc Compound (4)	Access	Acne	PLA (7)	Approved (8)	
Vitamin Mediated Delivery					
-----					
Oral Delivery System	Access	Various	Research	Pre-Clinical	
Folate Targeted Therapeutics	Access	Anti-tumor	Research	Pre-Clinical	
Vitamin B12 Targeted Therapeutics	Access	Anti-tumor	Research	Pre-Clinical	
Antiviral					
-----					
Anti viral compound (5)(6)	NIH	HIV	Development	Pre-Clinical	
Anti viral compound (6)	Rockefeller	HTLV type I	Development	Pre-Clinical	
	and II				

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

(2) Licensed from the School of Pharmacy, The University of London.

(3) Sold to GlaxoSmithKline. Subject to a Royalty Agreement. International rights (except Japan and Israel) licensed from GlaxoSmithKline subject to royalty and milestone payments.

(4) Licensed to Strakan.

(5) Licensed from NIH subject to royalty and milestone payments.

(6) Licensed from The Rockefeller University.

(7) United Kingdom ("U.K.") equivalent of an NDA.

(8) Marketing approval received from the Medicines Control Agency in the U.K. and product launched in March 2002.

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

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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 laboratories and investigators supervised and monitored by our employees. 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 a contract research organization will be engaged to perform this work.

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 \$4,174,000, \$4,007,000 and \$1,608,000 on research and development during the years 2001, 2000 and 1999, 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.

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

We have filed one U.S. and one PCT patent application for our bioerodeable hydrogel technology. A number of possible drug delivery systems can be developed using the Access bioerodible hydrogel 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 also have patent applications for our disc technology, mucoadhesive liquid technology and nanoparticle network delivery technology.

We have filed one U.S. 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 for our mucoadhesive liquid technology. Our applications cover a range of products utilizing our mucoadhesive liquid technology for the management of the various phases of mucositis. In addition to our product candidate, we also can incorporate an analgesic for pain management or compounds for the treatment of bacterial or fungal infections into our mucoadhesive liquid technology.

We have filed two patent applications for our nanoparticle delivery technology. These applications are the result of our collaboration with the University of North Texas, from which the technology has been licensed. The applications include a new class of gels. Our technology may lead to a variety of technological applications, including controlled delivery of drugs or other actives, optical and colorimetric sensors, interferometer systems, holographic or interference gratings, integrated circuit lithography, optical displays, environmental cleanup agents and bio-

adhesives.

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.

Through our Virologix subsidiary, we have two patents licensed from the National Institute of Health, or NIH, and four additional U.S. patent applications licensed from the Rockefeller University for our viral disease technology for the prevention and treatment of viral diseases including HIV. The licensed patents' compounds target a critical enzyme involved in viral infection and replication. The other patents include vaccines in HTLV type I and II infection, and other applications of the proprietary technology being used in the HIV therapeutic program.

We hold U.S. and European patents with broad composition of matter claims encompassing glycosaminoglycan, acidic saccharide, carbohydrate and other endothelial binding and targeting carriers in combination with drugs and diagnostic agents formulated by both physical and chemical covalent means. Eleven patents have issued commencing in 1990, ten U.S. and one European, and an additional two European patent applications are pending. These patents and applications relate to the in vivo medical uses of drugs and diagnostic carrier formulations which bind and cross endothelial and epithelial barriers at sites of disease, including but not limited to treatment and medical imaging of tumor, infarct, infection and inflammation. They further disclose the body's induction of endothelial, epithelial, tissue and blood adhesins, selectins, integrins, chemotaxins and cytotoxins at sites of disease as a mechanism for selective targeting, and they claim recognized usable carrier substances which selectively bind to these induced target determinants.

Under our various license agreements with GlaxoSmithKline, we have the worldwide rights for the use of amlexanox for the treatment of mucositis in patients undergoing chemotherapy and radiation treatment for cancer, and the worldwide rights, excluding Japan, the United States and Israel for the use of amlexanox for oral and dermatological use. GlaxoSmithKline has the rights to market any product developed for oral or dermatological use in the U.S.

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 well 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 doing 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 a considerable time period 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

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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 which has been shown to effectively bind and cross neovascular barriers and to penetrate the major classes of deep tissue and organ disease, which remain partially inaccessible to other technologies.

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

A number of companies are developing products to treat mucositis. Some of the products are in clinical trials that are further advanced than our product. These companies are Intrabiotics, Human Genome Sciences and Amgen. There is no current treatment to modify the symptoms of mucositis. There is a market to treat this disease.

Products developed from the 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 (TM), which is the first product developed utilizing the 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 & Upjohn; 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 which 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 27, 2002, we had 28 full time employees, 16 of whom have advanced scientific degrees. We believe 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.

## Other Developments

On October 19, 2001, our Board of Directors declared a special dividend distribution of a preferred share purchase right (a "Right") for each outstanding share of our common stock. This dividend was distributed on November 9, 2001 to our

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stockholders of record as of the close of business on that date. Each Right, when exercisable, generally entitles the registered holder to purchase from us one one-hundredth of a share of our Series A Junior Participating Preferred Stock at a price of \$30 per one one-hundredth of a share, subject to adjustment or substitution of our other securities in place of the preferred shares. The description and terms of the Rights are set forth in a Rights Agreement dated as of October 31, 2001, between us and American Stock Transfer & Trust Company.

## Risk Factors

With the exception of the historical information contained herein, the discussions herein contain forward-looking statements within the meaning of Section 27a of the Securities Act of 1933, as amended, that involve risks and uncertainties. Our actual results could differ from those discussed herein. Factors that could cause or contribute to such differences include, but are not limited to, risks discussed below as well as those discussed elsewhere herein and in documents incorporated herein by reference.

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 \$37.9 million through December 31, 2001. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop clinical candidates and from the associated administrative costs. We expect to incur significant 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.

We do not have significant operating revenue and we may never attain profitability.

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 our amlexanox products to date and we may not receive 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, market and obtain required regulatory approvals for any additional products. Moreover, even if we do identify, develop, commercialize, patent, manufacture, market and obtain required regulatory approvals for additional products, we may not receive 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 any amounts that we receive under strategic partnerships and research or drug development collaborations that we may establish and we cannot assure you that we

will be able to establish any such relationships on terms acceptable to us. We cannot assure you that we will achieve or maintain profitability in the future and our failure to receive significant revenues or to achieve profitable operations would impair our ability to sustain operations.

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. These risks include the possibilities that some or all of our drug candidates will be found to be unsafe or ineffective or otherwise fail to meet applicable regulatory standards or receive necessary regulatory clearances; that these drug candidates, if safe and effective will be difficult to develop into commercially viable drugs or to manufacture on a large scale or will be uneconomical to market; that proprietary rights of third parties will preclude us from marketing such drugs; or that third parties will market superior or equivalent drugs. Our failure to develop safe, commercially viable drugs would have a material adverse effect on our business, operating results and financial condition.

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. 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

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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. Although we believe that our existing capital resources, interest income and revenue from possible licensing agreements and collaborative agreements will be sufficient to fund our currently expected operating expenses and capital requirements for approximately three years, we may need to raise substantial additional capital during that period because our actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including :

- \* 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 may 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.

The success of our business may depend, in part, upon relationships with other companies.

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, if we successfully develop any commercially marketable pharmaceutical products, we may seek to enter joint venture, sublicense or 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 additional collaborative arrangements or license agreements as we may deem necessary to develop and commercialize 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.

We may depend upon contract manufacturers to assist us with the commercialization of any new products that we may develop.

We have no 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, so we 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 submission of products for regulatory approval and initiation of new development programs, which could cause our business to suffer. 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 could cause our business to suffer. 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

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applicable, to a manufacturing facility for the products until after 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 profit margins and our ability to develop and deliver such products on a timely and competitive basis.

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 drug candidates will require governmental approvals for commercialization, none of which have been obtained. 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. 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. We cannot assure you that the FDA or other regulatory approvals for any drug candidates will be granted 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, we, or 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. We cannot assure you that preclinical or clinical trials of any future drug candidates will 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 or animals 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. 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 and could cause our business, operating results and financial condition to suffer. For more information, see "Business-Government Regulation."

We may incur substantial product liability expenses due to the use or misuse of our products for which we may be unable to obtain complete 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

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liability insurance for the biotechnology industry is generally expensive, however, if available at all, and we cannot assure you that in the future we will be able to obtain insurance coverage at acceptable costs or in a sufficient amount, 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. Many of these competitors have and employ greater financial and other resources, including larger research and development staffs and more effective marketing and manufacturing organizations, than us or our collaborative partners. We cannot assure you that our competitors will not succeed in developing 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. We cannot assure you that drugs resulting from our research and development efforts or from our joint efforts with collaborative partners will be able to compete successfully 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 will 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. We cannot assure you that reimbursement in the United States or elsewhere will be available for any drugs that we may develop or, if available, will not be decreased in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our drugs, thereby adversely affecting our business. If reimbursement is not available or is available only to limited levels, we cannot assure you that we will be able to obtain collaborative partners to commercialize our drugs, or be able 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.

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 health care 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. Although we, together with our subsidiaries are either the owner or licensee of technology to 23 U.S. patents and to 17 U.S. patent applications now pending, and 6 European 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, we cannot assure you that any rights we may have under issued patents will provide us with significant protection against competitive products or otherwise be commercially viable. 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. 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. The loss of the services of one or more of these individuals could seriously impede our success. 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 no investment in manufacturing, production, marketing, product sales or regulatory compliance resources. If we develop pharmaceutical products that we will commercialize ourselves, however, we will need to hire additional personnel skilled in the clinical



testing and regulatory compliance process and in marketing and product sales. 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.

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Ownership of our shares is concentrated, to some extent, in the hands of a few individual investors.

Heartland Advisors, Inc., Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.), and Howard P. Milstein currently beneficially own approximately 13.3%, 9.5% and 5.8% respectively, of our issued and outstanding common stock.

Provisions of our charter documents could discourage an acquisition of our company that would benefit our stockholders.

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 of 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.

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. Currently, most of the outstanding shares of our common stock are unrestricted and freely tradable or tradable under Rule 144 or pursuant to a resale registration statement.

We may not be able to successfully integrate the targeted therapeutic technology business acquired from Biotech Australia into our business.

We expect that the February 2002 acquisition of the targeted therapeutic technology business of Biotech Australia Pty. Ltd. by our subsidiary, Access Pharmaceuticals Australia Pty. Ltd., will result in certain benefits including the development of a new drug delivery technology platform, an internal capability to perform biological studies which we previously out-sourced, which could enhance our ability to identify lead compounds more rapidly and develop the necessary preclinical data for regulatory filings and the achievement of the critical mass necessary for us to accelerate the development of our technology platforms. Our ability to achieve these and other expected benefits of the acquisition depends in part upon the integration of the newly acquired technology and personnel of Access Pharmaceuticals Australia with our technology, operations and personnel in a timely and efficient manner. We cannot assure you that we will be able to successfully integrate the targeted therapeutic technology business and the operations of our foreign subsidiary and its personnel with our business. In addition, we cannot assure you that our business will achieve improved revenues, efficiencies or synergies as a result of the acquisition.

#### Special Note Regarding Forward-Looking Statements

This Form 10-K contains forward-looking statements that involve risks and uncertainties. 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 this Form 10-K to conform such statements to actual results.

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ITEM 2. PROPERTIES

We maintain one facility of approximately 15,000 square feet for administrative offices and laboratories in Dallas, Texas. We have a lease agreement for the facility, which terminates in March 2006. However, we have an option for early termination. 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 6,000 square feet for offices and laboratories in New South Wales, Australia.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings.

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

None.

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PART II

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

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. From February 1, 1996 through March 29, 2000, our Common Stock traded on the OTC Bulletin Board, or OTCBB, under the trading symbol AXCS. The following table sets forth, for the periods indicated, the high and low closing prices for our common stock as reported by AMEX and the OTCBB for fiscal years 2001 and 2000. The OTCBB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

<TABLE>  
<CAPTION>

	Common Stock	
	High	Low
<S>	<C>	<C>
Fiscal Year Ended December 31, 2001		
First quarter	\$ 5.95	\$ 2.30
Second quarter	4.95	2.49
Third quarter	4.00	2.60
Fourth quarter	4.52	2.56

Fiscal Year Ended December 31, 2000

First quarter	\$ 13.88	\$ 1.63
Second quarter	7.31	3.00
Third quarter	7.25	2.50
Fourth quarter	9.00	4.88

</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 28, 2002 was approximately 5,500. On March 28, 2002, the closing price for the common stock as quoted on the AMEX was \$3.68. There were 13,051,734 shares of common stock outstanding at March 28, 2002.

#### Recent Sales of Unregistered Securities

None.

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#### ITEM 6. SELECTED FINANCIAL DATA (In Thousands, Except for Net Loss Per Share) (1)

The following data, insofar as it relates to each of the years in the five year period ended December 31, 2001, 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 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,				
	2001	2000	1999	1998	1997
<S>	<C>	<C>	<C>	<C>	<C>
Consolidated Statement of Operations Data:					
Total revenues	\$ 243	\$ 107	\$ 15	\$ -	\$ 435
Operating loss	(6,308)	(6,058)	(3,364)	(3,433)	(4,524)
Interest and miscellaneous income	1,451	972	53	58	119
Interest expense	1,170	342	12	22	36
Net loss	(6,027)	(5,428)	(3,308)	(3,397)	(4,441)
Common Stock Data:					
Net loss per basic and diluted common share	\$ (0.47)	\$ (0.49)	\$ (0.72)	\$ (1.28)	\$ (2.80)
Weighted average basic and diluted common shares outstanding	12,857	11,042	4,611	2,650	1,584

	December 31,				
	2001	2000	1999	1998	1997
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short term investments	\$20,126	\$25,809	\$ 869	\$ 1,487	\$ 438
Total assets	25,487	30,526	4,600	2,351	1,447
Deferred revenue	508	551	155	-	-
Convertible notes	13,530	13,530	-	-	-
Total liabilities	16,409	15,522	986	556	848
Total stockholders' equity	\$ 9,078	\$ 15,004	\$ 3,614	\$ 1,795	\$ 599

</TABLE>

(1) All share and per share amounts have been adjusted to reflect the one for twenty reverse stock split in June 1998.

On July 20, 1999, our wholly-owned subsidiary Access Holdings, Inc. merged with and into Virologix Corporation, a Delaware corporation ("Virologix"). As a result, Virologix became our wholly-owned subsidiary and each outstanding share of Virologix' common stock was converted into 0.231047 shares of our common stock, representing 999,963 shares of common stock. The transaction has been accounted for as a purchase. We assumed total assets of \$107,000 and trade and accrued payables of \$469,000. The aggregate purchase price has been allocated to the net assets acquired based on management's estimates of the fair values of assets acquired and liabilities assumed. The excess purchase price over the fair value of Virologix' net identifiable liabilities of \$2,464,000 was recorded as goodwill and is being amortized over ten years. Operations have been included in our consolidated financial statements since the date of acquisition.

On December 9, 1997, a wholly-owned subsidiary of ours merged with Tacora Corporation ("Tacora"), a Delaware corporation. As a result, Tacora became our wholly-owned subsidiary. The transaction has been accounted for as a purchase. The aggregate purchase price was \$739,000, payable \$124,000 in cash, \$192,000 in stock (representing 20,900 shares of Company common stock) and our assumption of \$239,000 in trade and accrued payables and

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\$184,000 of Tacora's capital lease obligations.

Certain milestones were met up to June 30, 2000 and we issued an aggregate of 49,609 shares of our common stock to certain former creditors of Tacora as a result. There are no further milestones related to this transaction to be met. The aggregate purchase price has been allocated to the net assets acquired based on management's estimates of the fair values of assets acquired and liabilities assumed. The excess purchase price over the fair value of Tacora's net identifiable assets of \$579,544 was recorded and written off in the fourth quarter of 1997 due to an impairment of the excess purchase price based on estimated future cash flows.

#### 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 in the development stage.

Together with our subsidiaries, we have proprietary patents or rights to seven drug delivery technology platforms: synthetic polymer targeted delivery, vitamin mediated targeted delivery (including oral), bioerodible hydrogel technology, nanoparticles and nanoparticle networks, Residerm (R) topical delivery, carbohydrate targeting technology and agents for the prevention and treatment of viral disease, including HIV. In addition, our partner GlaxoSmithKline, is marketing in the United States our jointly developed drug - Aphthasol (R), the first FDA approved product for the treatment of canker sores. We have licensed certain rights for the use of amlexanox in additional indications from GlaxoSmithKline for numerous, markets including the worldwide rights for mucositis and other products excluding the U.S. We are developing new formulations and delivery forms to evaluate amlexanox in additional clinical indications, including mucoadhesive disc delivery and mucoadhesive liquid delivery.

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, 2001, our accumulated deficit

was \$37,908,000, of which \$8,894,000 was the result of the write-off of excess purchase price.

## Results of Operations

### Comparison of Years Ended December 31, 2001 and 2000

Our revenue in 2001 was \$243,000, as compared to revenue of \$107,000 in 2000, an increase of \$136,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in 2001 was from several agreements, including agreements related to various amlexanox projects and Residerm (R) whereas the licensing revenue that we recognized in 2000 was only from amlexanox projects.

Our total research spending for the year ended December 31, 2001 was \$4,174,000, as compared to \$4,007,000 in 2000, an increase of \$167,000. The increase in expenses was the result of:

- \* higher salary and salary related expenses due to additional staff (\$461,000);
- \* higher development and clinical development costs for our polymer platinate project (\$195,000);
- \* higher clinical development costs (\$102,000) for amlexanox development projects for the cream and gel formulations;
- \* higher internal lab costs due to the additional staff and projects (\$52,000); and

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- \* other net increases (\$6,000).

These increases were offset by:

- \* lower clinical development costs for the following amlexanox projects: OraDisc (TM) (\$491,000) and OraRinse (TM) (\$80,000); and
- \* lower moving and recruiting expenses for scientific personnel (\$78,000).

We expect our research spending to increase and remain higher than it has been in prior years as we intend to hire additional scientific and clinical staff, commence additional clinical trials and accelerate preclinical development activities as we continue to develop our product candidates.

Our total general and administrative expenses were \$1,959,000 for 2001 and \$1,736,000 in 2000. Our general and administrative expenses increased \$223,000 in 2001 due to:

- \* higher patent and license expenses (\$118,000);
- \* higher shareholder expenses (\$95,000);
- \* executive search fee (\$30,000); and
- \* higher rent expenses (\$19,000); and
- \* other net increases (\$4,000).

These increases were offset by lower foreign tax expense (\$43,000).

Depreciation and amortization was \$418,000 in 2001 as compared to \$422,000 in 2000, a decrease of \$4,000.

Our loss from operations in 2001 was \$6,308,000 as compared to a loss of \$6,058,000 in 2000.

Our interest and miscellaneous income was \$1,451,000 for 2001 as compared to \$922,000 for 2000, an increase of \$479,000. The increase in interest income (\$403,000) was due to higher net cash balances in 2001 resulting from our private placements of common stock and our convertible note offering in the second half of 2000. The increase in miscellaneous income (\$76,000) was due entirely to a settlement in 2002 of a dispute with a vendor.

Interest expense was \$1,170,000 for 2001 as compared to \$342,000 for the same period in 2000, an increase of \$828,000. The increase in interest expense was due to interest accrued on the \$13.5 million convertible notes

issued in September 2000 and amortization of debt issuance costs.

Net loss for 2001 was \$6,027,000, or a \$0.47 basic and diluted loss per common share compared with a loss of \$5,428,000, or a \$0.49 basic and diluted loss per common share, for 2000.

#### Comparison of Years Ended December 31, 2000 and 1999

Our revenue in 2000 was \$107,000, as compared to revenue of \$15,000 in 1999, an increase of \$92,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in 2000 was from several amlexanox agreements. Revenues in 1999 were for an option payment on our carbohydrate polymer technology as applied to the field of selectively replicating viruses.

Our total research spending for the year ended December 31, 2000 was \$4,007,000, as compared to \$1,608,000 in 1999, an increase of \$2,399,000. The increase in expenses was the result of:

- \* higher clinical development and product development costs for the following amlexanox projects: OraDisc (TM) (\$792,000), OraRinse (TM) (\$497,000), amlexanox cream (\$159,000) and amlexanox gel (\$113,000);
- \* higher external development costs for our polymer platinate project (\$376,000);
- \* higher salary and salary related expenses due to additional staff (\$223,000);

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- \* higher development costs for our hydrogel project (\$72,000);
- \* additional travel expenses (\$52,000);
- \* moving expenses for scientific personal (\$56,000); and
- \* recruitment expenses (\$59,000).

Our total general and administrative expenses were \$1,736,000 for 2000 and \$1,471,000 in 1999. Our general and administrative expenses increased in 2000 due to:

- \* higher salary and bonus expenses (\$307,000);
- \* higher legal and accounting expenses (\$107,000);
- \* higher listing fees due to our listing on the American Stock Exchange (\$49,000);
- \* foreign taxes paid on licensing fees received (\$43,000);
- \* lease expenses for office rent, office equipment and computers and office and equipment maintenance (\$41,000); and
- \* other net increases (\$22,000).

These increases were offset by:

- \* a reduction in warrant costs (\$249,000) due to fewer warrants granted to consultants in 2000; and
- \* lower patent expenses (\$55,000).

Depreciation and amortization was \$422,000 in 2000 as compared to \$285,000 in 1999, an increase of \$137,000. The increase in amortization was due to:

- \* additional amortization of goodwill of \$143,000 recorded in 2000 versus 1999 as a result of the acquisition of Virologix Corporation in July 1999; and
- \* additional amortization of licenses totaling \$58,000 due to additional licenses purchased and a full twelve months amortization in 2000 of the licenses acquired in 1999.

These increases were offset by lower depreciation (\$64,000), reflecting that a number of our major assets have been fully depreciated.

Our loss from operations in 2000 was \$6,058,000 as compared to a loss of \$3,349,000 in 1999.

Our interest and miscellaneous income was \$972,000 for 2000 as

compared to \$53,000 for 1999, an increase of \$919,000. The increase in interest income was due to higher cash balances in 2000 resulting from our private placements of common stock and our convertible note offering in 2000.

Interest expense was \$342,000 for 2000 as compared to \$12,000 for the same period in 1999, an increase of \$330,000. The increase in interest expense is due to interest accrued on the \$13.5 million convertible notes issued in September 2000 and amortization of debt issuance costs.

Our net loss for 2000 was \$5,428,000, or a \$0.49 basic and diluted loss per common share, compared with a loss of \$3,308,000, or a \$0.72 basic and diluted loss per common share for 1999.

#### 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, 2001 our cash and cash

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equivalents were \$20,126,000 and our working capital was \$18,519,000. Our working capital at December 31, 2001 represented a decrease of \$5,878,000 as compared to our working capital as of December 31, 2000 of \$24,397,000. This decrease was due to our overall operating expenses and the interest accrued on the \$13.5 million convertible notes.

We have 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, 2001 of \$37,908,000. We expect that our existing capital resources will be adequate to fund our current level of operations through June 2004. We cannot assure you that we will ever be able to generate product revenue or achieve or sustain profitability.

We will 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 newly acquired and developed technology. Our future capital requirements and adequacy of available funds will depend on many factors, including:

- \* the successful commercialization of amlexanox and Zindaclin (TM);
- \* the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- \* the successful integration of our newly created subsidiary, Access Pharmaceuticals Australia Pty. Limited;
- \* 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;
- \* 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.

At December 31, 2001, we had invested in the following projects approximately \$7,281,000 for Polymer Platinate (AP 5280), \$2,540,000 for OraDisc (TM) and \$1,175,000 for OraRinse (TM) and Mucoadhesive Liquid Technology. We discussed in Part I of this Form 10-K the status of each project, the efforts and timing that are necessary for the next step of each project and risks associated with our developments. We cannot at this time reasonably estimate the cost to complete each project due to uncertainties in the development process as discussed in Risk Factors in Part I of this Form 10-K.

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, none of which matures in more than two years. We do not invest in derivative financial instruments, as defined by Statement of Financial Accounting Standards No. 133 and 138.

#### Critical Accounting Policies

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States 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 often must make individual estimates and assumptions regarding expected outcomes or uncertainties. As you might expect, the actual results or outcomes are generally 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.

We periodically review the carrying value of our goodwill and other intangible assets when events and circumstances warrant such a review. One of the methods used for this review is performed using estimates of future cash flows. If the carrying value of our goodwill or other intangible assets are considered impaired, an impairment charge is recorded for the amount by which the carrying value of the goodwill or other intangible assets exceeds its fair value. We believe that the estimates of future cash flows and fair value are reasonable. Changes in estimates of such cash flows and fair value, however, could affect the calculation.

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 risk factors, such as those discussed elsewhere in this report, could not adversely impact our consolidated financial position, results of operations or cash flows.

#### New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard No. 141, "Business Combination" (FAS 141) and Statement of Financial Accounting Standard No. 142, "Goodwill and Other Intangible Assets" (FAS 142). FAS 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. FAS 141 further clarifies the criteria to recognize intangible assets separately from goodwill. The requirements of FAS 141 are effective for any business combination accounted for by the purchase method that is completed after June 30, 2001. Under FAS 142, goodwill and indefinite-lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Separable intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful lives. Goodwill recognized prior to July 1, 2001 is required to be amortized through December 31, 2001.

We do not believe that the adoption of FAS 141 will have any material impact on our financial position or results of operations. When we adopt FAS 142 in January 2002, annual and quarterly goodwill amortization of \$246,000 and \$61,500 will no longer be recognized. In 2002, we will complete a transitional fair value based impairment test of goodwill. Impairment losses, if any, resulting from transitional testing will be recognized.



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 2002 and 2003 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 \$84,000. The estimated effect assumes no changes in our short-term investments at December 31, 2001. 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 are included at Item 14.

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

None.

### 30 PART III

#### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE COMPANY

The information required by this item with respect to directors and reports of beneficial ownership will be contained in our definitive Proxy Statement ("Proxy Statement") for our 2002 Annual Meeting of Stockholders to be held on May 20, 2002 and is incorporated herein by reference. We will file the Proxy Statement with the Securities and Exchange Commission not later than April 30, 2002.

#### 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.

### PART IV

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

##### a. Financial Statements and Exhibits

##### Page

1. Financial Statements. The following financial statements are submitted as part of this report:

Report of Independent Certified Public Accountants	F-1
Consolidated Balance Sheets at December 31, 2001 and 2000	F-2
Consolidated Statements of Operations for 2001, 2000 and 1999 and the period from February 24, 1988 (Inception) to December 31, 2001	F-3
Consolidated Statements of Stockholders' Equity (Deficit) for the period from February 24, 1988 (Inception) to December 31, 2001	F-4
Consolidated Statements of Cash Flows for 2001, 2000 and 1999 and the period from February 24, 1988 (Inception) to December 31, 2001	F-8
Notes to Consolidated Financial Statements	F-9

##### 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.

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### 3. Exhibits

#### Exhibit Number

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. 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)

\*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 Stockholder's Agreement dated October 1995 between us and Dr. David F. Ranney (Incorporated by reference to Exhibit A of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031).

10.5 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)

10.6 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)

10.7 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)

10.8 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)

10.9 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)

10.10 License Agreement between The Dow Chemical Company and us dated June 30, 1997. (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 September 30, 1997)

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### 3.0 Exhibits (continued)

#### Exhibit Number

10.10 License Agreement between Strakan 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)

10.12 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)

\*10.13 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)

10.14 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)

10.15 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)

10.16 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)

\*10.17 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)

\*10.18 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10K for the year ended December 31, 1999)

\*10.19 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)

10.20 Form of Convertible Note (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)

10.21 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)

10.22 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)

\*10.23 2001 Restricted Stock Plan (incorporated by reference to Appendix A of our Proxy Statement filed on April 16, 2001)

10.24 Supplemental Lease Agreement between Pollock Realty Corporation and us dated September 15, 2002.

10.25 Amendment to 1995 Stock Option Plan

21. Subsidiaries of the registrant

23.0 Consent of Experts and Counsel

23.1 Consent of Grant Thornton LLP

\* Management contract or compensatory plan required to be filed as an Exhibit to this Form pursuant to Item 14(c) of the report

(b) Reports on Form 8-K

None

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SIGNATURES  
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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 April 1, 2002 By: /s/ Kerry P. Gray

-----  
Kerry P. Gray  
President and Chief Executive  
Officer

Date April 1, 2002 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 April 1, 2002 By: /s/ Kerry P. Gray

-----  
Kerry P. Gray  
President and Chief Executive  
Officer, Director

Date April 1, 2002 By: /s/ J. Michael Flinn

-----  
J. Michael Flinn, Director

Date April 1, 2002 By: /s/ Stephen B. Howell

-----  
Stephen B. Howell, Director

Date April 1, 2002 By: /s/ Max Link

-----  
Max Link, Director

Date April 1, 2002 By: /s/ Herbert H. McDade, Jr.

-----  
Herbert H. McDade, Jr., Director

Date April 1, 2002 By: /s/ John J. Meakem

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John J. Meakem, Jr., Director

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Report of Independent Certified Public Accountants

Board of Directors and Stockholders  
Access Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Access Pharmaceuticals, Inc. and Subsidiaries (a development stage company) as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2001 and for the period February 24, 1988 (inception) to December 31, 2001. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Access Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2001 and 2000, and the consolidated results of their operations and their consolidated cash flows for each of the three years in the period ended December 31, 2001 and for the period February 24, 1988 to December 31, 2001, in conformity with accounting principles generally accepted in the United States of America.

/s/ Grant Thornton LLP

-----  
GRANT THORNTON LLP

Dallas, Texas  
February 22, 2002

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

CONSOLIDATED BALANCE SHEETS  
December 31,

<TABLE>

<CAPTION>

ASSETS	2001	2000
	-----	-----
<S>	<C>	<C>
Current assets		
Cash and cash equivalents	\$ 7,426,000	\$ 8,415,000
Short term investments, at cost	12,700,000	17,394,000
Accounts receivable	83,000	251,000
Accrued interest receivable	110,000	196,000
Prepaid expenses and other current assets	611,000	133,000
	-----	-----

Total current assets	20,930,000	26,389,000
Property and equipment, net	477,000	116,000
Debt issuance costs, net	679,000	861,000
Licenses, net	774,000	887,000
Goodwill, net	1,868,000	2,115,000
Other assets	759,000	158,000
Total assets	<u>\$25,487,000</u>	<u>\$30,526,000</u>

#### LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities		
Accounts payable and accrued expenses	\$ 1,486,000	\$ 1,158,000
Accrued interest payable	310,000	283,000
Deferred revenues	508,000	551,000
Current portion of note payable	107,000	-
Total current liabilities	<u>2,411,000</u>	<u>1,992,000</u>
Note payable, net of current portion	468,000	-
Convertible notes	13,530,000	13,530,000
Total liabilities	<u>16,409,000</u>	<u>15,522,000</u>
Commitments and contingencies	-	-
Stockholders' equity		
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, 12,909,344 at December 31, 2001 and 12,844,699 at December 31, 2000	132,000	132,000
Additional paid-in capital	48,057,000	47,802,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Unamortized value of restricted stock grants	(154,000)	-
Treasury stock, at cost - 819 shares	(4,000)	(4,000)
Deficit accumulated during the development stage	(37,908,000)	(31,881,000)
Total stockholders' equity	<u>9,078,000</u>	<u>15,004,000</u>
Total liabilities and stockholders' equity	<u>\$25,487,000</u>	<u>\$30,526,000</u>

</TABLE>

The accompanying notes are an integral part of these statements.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

#### CONSOLIDATED STATEMENTS OF OPERATIONS

<TABLE>

<CAPTION>

	February 24, 1988			
	Year ended December 31,		(inception) to	
	December 31,		December 31,	
	2001	2000	1999	2001
	-----	-----	-----	-----

<S>

Revenues

<C> <C> <C> <C>

Research and development	\$	-	\$	-	\$	-	\$	2,711,000
Option income	-	-	15,000	2,164,000				
Licensing revenues	243,000	107,000	-	675,000				
	-----							
Total revenues	243,000	107,000	15,000	5,550,000				
Expenses								
Research and development	4,174,000	4,007,000	1,608,000	20,154,000				
General and administrative	1,959,000	1,736,000	1,471,000	13,620,000				
Depreciation and amortization	418,000	422,000	285,000	2,394,000				
Write-off of excess purchase price	-	-	-	8,894,000				
	-----							
Total expenses	6,551,000	6,165,000	3,364,000	45,062,000				
Loss from operations	(6,308,000)	(6,058,000)	(3,349,000)	(39,512,000)				
Other income (expense)								
Interest and miscellaneous income	1,451,000	972,000	53,000	3,308,000				
Interest and debt expense	(1,170,000)	(342,000)	(12,000)	(1,704,000)				
	-----							
	281,000	630,000	41,000	1,604,000				
	-----							
Net loss	\$(6,027,000)	\$(5,428,000)	\$(3,308,000)	\$(37,908,000)				
	=====							
Basic and diluted loss								
per common share	\$(0.47)	\$(0.49)	\$(0.72)					
	=====							
Weighted average basic and diluted								
common shares outstanding	12,856,639	11,042,141	4,611,315					
	=====							

</TABLE>

The accompanying notes are an integral part of these statements.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

#### CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

<TABLE>

<CAPTION>

	Common Stock	Notes	Unamortized	Deficit			
	Shares	paid-in	value of	accumulated	Treasury	restricted	during the
	Amount	capital	Additional	restricted	stock	grants	development
			receivable	stock			stage
			from	stock			
			stockholders	holders			
<S>	<C>	<C>	<C>	<C>	<C>	<C>	<C>
Balance, February 24, 1988	-	\$	-	\$	-	\$	-
Common stock issued, \$6.60 per share	15,000	-	97,000	-	-	-	-
Common stock issued, \$1.60 per share	8,000	-	12,000	-	-	-	-
Net loss for the period February 24, 1988 to December 31, 1988	-	-	-	-	-	-	(30,000)
	-----						
Balance, December 31, 1988	23,000	-	109,000	-	-	-	(30,000)
Common stock issued, \$6.60 per share	4,000	-	29,000	-	-	-	-
Common stock issued, \$33.00 per share	4,000	-	124,000	-	-	-	-
Common stock issued, \$0.20 per share	97,000	1,000	8,000	-	-	-	-
Net loss for the year	-	-	-	-	-	-	(191,000)
	-----						
Balance, December 31, 1989	128,000	1,000	270,000	-	-	-	(221,000)









The accompanying notes are an integral part of this statement.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

CONSOLIDATED STATEMENTS OF CASH FLOWS

<TABLE>  
<CAPTION>

	February 24, 1988 (inception) to			
	Year ended December 31,		December 31,	
	2001	2000	1999	2001
<S>	<C>	<C>	<C>	<C>
Cash flows from operating activities:				
Net loss	\$(6,027,000)	\$(5,428,000)	\$(3,308,000)	\$(37,908,000)
Adjustments to reconcile net loss to net cash used in operating activities:				
Write off of excess purchase price	-	-	-	8,894,000
Warrants issued in payment of consulting expenses	41,000	64,000	296,000	970,000
Research expenses related to common stock granted	-	-	-	100,000
Amortization of restricted stock grants	27,000	-	-	27,000
Depreciation and amortization	418,000	422,000	285,000	2,394,000
Amortization of debt costs	182,000	54,000	-	236,000
Deferred revenue	(43,000)	396,000	155,000	398,000
Change in operating assets and liabilities:				
Accounts receivable	168,000	(163,000)	(88,000)	(84,000)
Accrued interest receivable	86,000	(196,000)	-	(110,000)
Prepaid expenses and other current assets	(478,000)	(16,000)	(63,000)	(612,000)
Licenses	-	(100,000)	(425,000)	(525,000)
Other assets	(1,000)	-	-	(7,000)
Accounts payable and accrued expenses	328,000	353,000	(97,000)	724,000
Accrued interest payable	27,000	283,000	-	310,000
Net cash used in operating activities	(5,272,000)	(4,331,000)	(3,245,000)	(25,193,000)
Cash flows from investing activities:				
Capital expenditures	(419,000)	(72,000)	(5,000)	(1,664,000)
Sales of capital equipment	-	-	-	15,000
Redemptions (purchases) of short-term investments and certificates of deposit, net	4,094,000	(17,394,000)	-	(13,300,000)
Purchase of businesses, net of cash acquired	-	-	(102,000)	(226,000)
Other investing activities	-	-	-	(150,000)
Net cash provided by (used in) investing activities	3,675,000	(17,466,000)	(107,000)	(15,325,000)
Cash flows from financing activities:				
Proceeds from notes payable	600,000	-	-	1,321,000
Payments of notes payable	(25,000)	(26,000)	(97,000)	(775,000)
Purchase of treasury stock	-	(754,000)	-	(754,000)
Cash acquired in merger with Chemex	-	-	-	1,587,000
Notes receivable from shareholders	-	(1,045,000)	-	(1,045,000)
Proceeds from convertible note, net	-	12,615,000	-	12,615,000
Proceeds from stock issuances, net	33,000	18,553,000	2,831,000	34,995,000
Net cash provided by financing activities	608,000	29,343,000	2,734,000	47,944,000
Net increase (decrease) in cash and cash equivalents	(989,000)	7,546,000	(618,000)	7,426,000
Cash and cash equivalents at beginning of period	8,415,000	869,000	1,487,000	-

Cash and cash equivalents at end of period	\$7,426,000	\$8,415,000	\$869,000	\$7,426,000
---	-------------	-------------	-----------	-------------

</TABLE>

The accompanying notes are an integral part of these statements.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
Three years ended December 31, 2001

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. We operate in a single industry segment. We are in the development stage and our efforts have been principally devoted to research and development, resulting in significant losses since inception on February 24, 1988.

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 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 and 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 accretions 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. Assets acquired pursuant to capital lease arrangements are amortized over the shorter of the estimated useful lives or the lease terms.

Patents and Applications

We expense 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.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

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

Licenses

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

\*In 1999, we acquired a license from the National Institutes of Health for \$330,000. The license is amortized over ten years.

\*In 1999, we also acquired the rights to develop amlexanox for other indications for \$200,000 and future milestone payments and royalties. The license is amortized over ten years.

\*In 2000, we paid an additional \$100,000 for the rights to develop amlexanox for other indications. The license is amortized over ten years.

Long-term Investments

In 1997, we signed an agreement with CepTor Corporation ("CepTor"), a privately held biotechnology company. Under the terms of the agreement, which is now terminated, we purchased an aggregate of 25,000 shares of common stock for \$150,000.

Revenue Recognition

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 unearned revenue until the related research activities are performed. 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. Many of our agreements are for ten years with automatic extensions. Option revenues are recognized when the earnings process is completed pursuant to the terms of the respective contract.

Research and Development Expenses

Research and development costs are expensed as incurred.

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.

Loss Per Share

In accordance with the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 128, "Earnings 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. Dilutive potential common shares result from stock options and warrants. However, for all years

presented, stock options and warrants are anti-dilutive.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

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

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 evaluate the realizability of goodwill based on management's best estimates of future cash flows from operations. It is at least reasonably possible that the estimates used by us to evaluate the realizability of goodwill, will be materially different from actual amounts or results.

These differences could result in the impairment of all or a portion our goodwill, which could have a materially adverse effect on our operations.

Stock Option Plans

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. As such, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeds the exercise price. 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.

Impairment of Long-Lived Assets and Long-Lived Assets to Be Disposed Of

SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and Long-Lived Assets to Be Disposed Of, requires that long-lived assets and certain identifiable intangibles be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceed the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

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 as a basis to value our debt.

New Accounting Pronouncements

In July 2001, the Financial Accounting Standards Board issued Statement of Financial Accounting Standard No. 141, "Business Combination" (FAS 141) and Statement of Financial Accounting Standard No. 142, "Goodwill and Other Intangible Assets" (FAS 142). FAS 141 eliminates the pooling-of-interests method of accounting for business combinations except for qualifying business combinations that were initiated prior to July 1, 2001. FAS 141 further clarifies the criteria to recognize intangible assets

separately from goodwill. The requirements of FAS 141 are effective for any business combination accounted for by the purchase method that is completed after June 30, 2001 (i.e., the acquisition date is July 1, 2001 or thereafter). Under FAS 142, goodwill and indefinite-lived intangible assets are no longer amortized but are reviewed annually (or more frequently if impairment indicators arise) for impairment. Separable intangible assets that are not deemed to have an indefinite life will continue to be amortized over their useful

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Access Pharmaceuticals, Inc. and Subsidiaries  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

New Accounting Pronouncements - continued

lives. Goodwill recognized prior to July 1, 2001 is required to be amortized through December 31, 2001.

We do not believe that the adoption of FAS 141 will have any material impact on our financial position or results of operations. When we adopt FAS 142 in January 2002, annual and quarterly goodwill amortization of \$246,000 and \$61,500, respectively, will no longer be recognized. We will complete a transitional fair value based impairment test of goodwill in 2002. Impairment losses, if any, resulting from transitional testing will be recognized.

NOTE 2 - SHORT-TERM INVESTMENTS

Short-term investments consist of certificates of deposit maturing from March 2002 through March 2003.

NOTE 3 - ACQUISITIONS

On July 20, 1999, our wholly-owned subsidiary Access Holdings, Inc. merged with and into Virologix Corporation, a Delaware corporation ("Virologix"). As a result, Virologix became a wholly-owned subsidiary and each outstanding share of Virologix' common stock was converted into 0.231047 shares of our common stock, representing 999,963 shares of common stock. The transaction has been accounted for as a purchase. The aggregate purchase price has been allocated to the net assets acquired based on management's estimates of the fair values of assets acquired and liabilities assumed. The excess purchase price over the fair value of Virologix' net identifiable assets of \$2,464,000 was recorded as goodwill and is being amortized over ten years. Operations have been included in our consolidated financial statements since the date of acquisition.

NOTE 4 - RELATED PARTY TRANSACTIONS

Under a consulting agreement between Thoma Corporation ("Thoma") and us, Thoma receives payments for consulting services and reimbursement of direct expenses. Herbert H. McDade, Jr., our 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
2001	\$ 54,000	\$ -
2000	72,000	1,000
1999	72,000	9,000

</TABLE>

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	Exercise Warrants	Price
<S>	<C>	<C>	<C>	<C>
2001	\$101,000	\$ 16,000	15,000	\$3.00
2000	66,000	9,000	30,000	\$2.00
1999	62,000	18,000	30,000	\$3.00

</TABLE>

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Access Pharmaceuticals, Inc. and Subsidiaries  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 4 - RELATED PARTY TRANSACTIONS - continued

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 for \$1,045,000 as a reduction of equity in the Consolidated Balance Sheet.

The stock granted under the Program other than to the corporate secretary vests ratably over a four year period. The stock granted to the corporate secretary vested on grant.

NOTE 5 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

<TABLE>  
<CAPTION>

	December 31,	
	2001	2000
<S>	<C>	<C>
Laboratory equipment	\$1,139,000	\$ 848,000
Laboratory and building improvements	151,000	50,000
Furniture and equipment	179,000	190,000
	1,469,000	1,088,000
Less accumulated depreciation and amortization	992,000	972,000
Net property and equipment	\$ 477,000	\$ 116,000

</TABLE>

Depreciation and amortization on property and equipment was \$57,000, \$64,000, and \$121,000 for the years ended December 31, 2001, 2000 and 1999, respectively.

NOTE 6 - 401(k) PLAN

We implemented a tax-qualified employee savings and retirement plan (the



"401(k) Plan") on January 1, 1999 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 (\$11,000 in 2002, \$10,500 in 2001 and 2000) and to have the amount of such reduction contributed to the 401(k) Plan. Effective May 1, 1999, we implemented a 401(k) matching program whereby we contribute for each dollar a participant contributes, 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 \$32,000 in 2001, \$22,000 in 2000 and \$13,000 in 1999.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 2001

NOTE 7 - NOTE PAYABLE

On September 20, 2001, we completed a \$600,000 installment loan with a bank. 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 \$600,000 certificate of deposit classified as an other asset at December 31, 2001.

Future maturities of the note payable are as follows:

<TABLE>

<S>	<C>
2002	\$ 107,000
2003	114,000
2004	121,000
2005	130,000
2006	103,000
	-----
	\$ 575,000
	=====

</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. The notes have a fixed conversion price of \$5.50 per share of common stock and were not convertible for the first twelve months. The note bore interest at 7.0% per annum for the first twelve months and was adjusted to 7.7% interest per annum for the remainder of the time the notes are outstanding. The notes are due September 13, 2005. Total expenses of issuance were \$915,000 and are amortized over the life of the notes.

NOTE 9 - COMMITMENTS

At December 31, 2000, we do not have any capital lease obligations. We do have commitments under noncancelable operating leases for facilities and equipment as follows:

<TABLE>

<CAPTION>

<S>	Operating leases <C>
2002	\$ 146,000
2003	159,000
2006	155,000

2007	149,000
Thereafter	37,000
	-----
Total future minimum lease payments	\$ 646,000
	=====

</TABLE>

We lease certain office and research and development facilities under an operating lease. Rent expense for the years ended December 31, 2001, 2000 and 1999 was \$114,000, \$85,000 and \$81,000, respectively.

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Access Pharmaceuticals, Inc. and Subsidiaries  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 10 - STOCKHOLDERS' EQUITY

Common Stock

In May 2000 we completed two self-managed private placement sales of our common stock, at prices of \$3.00 and \$5.00 per share, respectively. We received gross proceeds of \$3.3 million from these sales.

On March 1, 2000, with the assistance of an investment bank, we completed the closing of a private placement offering of 4.8 million shares of common stock, at a per share price of \$2.50, for which we received gross proceeds of \$12.0 million. The placement agent for the offering received warrants to purchase 509,097 shares of common stock with an exercise price of \$2.50 per share, in accordance with the offering terms, and elected to receive 382,315 shares of common stock in lieu of certain sales commissions and expenses.

On July 20, 1999 and October 18, 1999, with the assistance of an investment bank, we completed the first and second closings of an offering of an aggregate of 1,551,000 shares of common stock at a per share price of \$2.00, receiving aggregate gross proceeds of \$3.1 million, less issuance costs of \$271,000. The placement agent for the offering received warrants to purchase 165,721 shares of common stock with an exercise price of \$2.00 per share, in accordance with the offering terms, and elected to receive 106,217 shares of common stock in lieu of certain sales commissions and expenses.

Restricted Stock Purchase Program

See Note 4 for a discussion of our Restricted Stock Purchase Program.

Warrants

There were warrants to purchase a total of 1,061,798 shares of common stock outstanding at December 31, 2001. All the warrants were exercisable at December 31, 2001. The warrants had various prices and terms as follows:

<TABLE>  
<CAPTION>

Summary of Warrants	Warrants Outstanding	Exercise Price	Expiration Date
	<C>	<C>	<C>
2001 scientific consultant (a)	15,000	\$ 3.00	1/1/08
2000 offering (b)	353,137	2.00	3/01/05
2000 scientific consultant (c)	30,000	2.00	1/01/07
2000 scientific consultant (d)	7,500	3.00	1/01/04
1999 offering (e)	120,858	2.00	10/18/04
1999 warrants assumed in merger (f)	27,145	12.98	4/30/02

1999 financial advisor (g)	100,000	2.93	3/26/04
1999 scientific consultant (h)	30,000	3.00	1/01/03
1998 offering (i)	325,658	3.00	7/30/03
1998 financial advisor (j)	15,000	4.00	12/01/03
1997 financial advisor (k)	37,500	7.50/9.00	6/30/02
	-----		
Total	1,061,798		
	=====		

</TABLE>

a) During 2001, 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 an expected life of 7 years. Total fair value of the warrants relating to the

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 10 - STOCKHOLDERS' EQUITY - Continued

consulting services (\$41,000) has been recorded as consulting expense and an increase to additional paid-in capital.

b) In connection with the aforementioned 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.

c) During 2000, a scientific advisor received warrants to purchase 30,000 shares of common stock at an exercise price of \$2.00 per share at any time from January 1, 2000 until January 1, 2007, for scientific consulting services rendered in 2000. The fair value of the warrants was \$1.68 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 5.625%, expected volatility 118% and an expected life of 5 years. Total fair value of the warrants relating to the consulting services (\$50,000) has been recorded as consulting expense and an increase to additional paid-in capital.

(d) During 2000, a scientific advisor received warrants to purchase 7,500 shares of common stock at any time from January 1, 1999 until January 1, 2004, for scientific consulting services rendered in 2000. The fair value of the warrants was \$1.87 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 5.38%, expected volatility 122% and an expected life of 4 years. Total fair value of the warrants relating to the consulting services (\$14,000) has been recorded as consulting expense and an increase to additional paid-in capital.

(e) In connection with the aforementioned offerings of common stock in 1999, warrants to purchase a total of 165,721 shares of common stock were issued. All of the warrants are exercisable immediately and expire five years from date of issuance.

(f) In connection with the aforementioned merger with Virologix, we assumed warrants to purchase 27,145 shares of common stock. Virologix warrants were converted into 0.231047 Access warrants. All of the warrants are exercisable immediately at \$12.98 per share and expire between March 24, 2002 and November 1, 2002.

(g) During 1999, a financial advisor received warrants to purchase 100,000 shares of common stock at any time from March 26, 1999 until March 26, 2004, for financial consulting services rendered in 1999. The fair value of the warrants was \$2.48 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 5.42%, expected volatility 122% and an expected life of 5 years. Total fair value of the warrants relating to the consulting services (\$249,000) has been recorded as general and administrative expense and an increase to additional paid-in capital.

(h) During 1999, a scientific advisor received warrants to purchase 30,000 shares of common stock at any time from January 1, 1999 until January 1, 2003, for scientific consulting services rendered in 1999. The fair value of the warrants was \$1.56 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 5.38%, expected volatility 122% and an expected life of 4 years. Total fair value of the warrants relating to the consulting services (\$47,000) has been recorded as consulting expense and an increase to additional paid-in capital.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 10 - STOCKHOLDERS' EQUITY - Continued

(i) In connection with offerings of units and common stock in 1998, warrants to purchase a total of 579,627 shares of common stock were issued. All of the warrants are exercisable immediately at \$3.00 per share and expire five years from date of issuance.

(j) During 1998, a financial advisor received warrants to purchase 15,000 shares of common stock at any time from December 1, 1998 until December 1, 2003, for financial consulting services rendered in 1998. The fair value of the warrants was \$2.48 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 4.85%, expected volatility 122% and an expected life of 5 years. Total fair value of the warrants relating to the consulting services (\$37,000) has been recorded as general and administrative expense and an increase to additional paid-in capital.

(k) We also have warrants outstanding to purchase 37,500 shares of common stock, one-half (18,750 shares) at an exercise price of \$7.50 per share, and one-half (18,750 shares) at an exercise price of \$9.00 per share until June 30, 2002.

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, 2001 there were 44,639 shares granted and 155,361 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 2,000,000 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, 2001, there were 671,500 additional shares available for grant under the 1995 Stock Awards Plan.

We apply APB Opinion No. 25 in accounting for our stock options. Accordingly, no compensation expense has been recognized in the accompanying Consolidated Statements of Operations for employee stock options because the quoted market price of the underlying common stock did not exceed the exercise price of the option at the date of grant. Had we determined compensation cost based on the fair value at the grant date for stock options issued after 1994 under SFAS No. 123, our net loss and loss per share would have been increased to the pro forma amounts indicated below:

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 11 - STOCK OPTION PLANS - Continued

<TABLE>  
<CAPTION>

	December 31,		
	2001	2000	1999
<S>	<C>	<C>	<C>
Net loss			
As reported	\$(6,027,000)	\$(5,428,000)	\$(3,308,000)
Pro forma	(7,592,000)	(6,366,000)	(3,603,000)
Basic and diluted loss per share			
As reported	(\$.47)	(\$.49)	(\$.72)
Pro forma	(\$.59)	(\$.57)	(\$.78)

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 2001, 2000 and 1999, respectively: dividend yield of 0% for all periods; volatility of 90%, 118% and 91%; risk-free interest rates of 3.70%, 4.85% and 6.62% and expected lives of four years for all periods. The weighted average fair values of options granted were \$2.52, \$2.88 and \$1.37 per share during 2001, 2000 and 1999, 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, 1999	306,500	\$ 3.00	
Granted	333,000	1.99	
Forfeited	(6,500)	(1.46)	
Outstanding options at December 31, 1999	633,000	2.47	
Granted	551,500	4.94	
Exercised	(47,916)	2.64	
Forfeited	(10,000)	1.73	
Outstanding options at December 31, 2000	1,126,584	3.68	
Granted	154,000	3.65	

-----  
 Outstanding options at December 31, 2001 1,280,584 \$3.68  
 =====

Exercisable at December 31, 1999 300,875 \$2.66  
 Exercisable at December 31, 2000 414,239 2.59  
 Exercisable at December 31, 2001 733,851 3.20

</TABLE>

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 Access Pharmaceuticals, Inc. and Subsidiaries  
 (a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
 Three years ended December 31, 2001

NOTE 11 - STOCK OPTION PLANS - Continued

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2001 is summarized below:

<TABLE>  
 <CAPTION>

Range of exercise prices	Weighted average		Weighted-		
	Number of shares	Remaining life in years	Exercise price	Number of shares	average exercise price
<S>	<C>	<C>	<C>	<C>	<C>
\$2.00	304,000	8.0	\$2.00	232,156	\$2.00
\$2.50-2.76	199,500	9.3	2.57	65,404	2.50
\$2.94-3.99	341,084	7.5	3.09	269,520	3.03
\$4.05-7.8125	436,000	9.1	5.88	166,771	5.43
	-----		-----		
	1,280,584		733,851		
	=====		=====		

</TABLE>

Summarized information for the 2000 Special Stock Option Plan is as follows:

<TABLE>  
 <CAPTION>

<S>	Weighted- average exercise price	
	Shares	price
	<C>	<C>
Outstanding options at January 1, 2000	-	
Granted	500,000	\$2.50
	-----	
Outstanding options at December 31, 2000	500,000	\$2.50
	=====	

</TABLE>

218,749 of the options in the 2000 Special Stock Option Plan were exercisable at December 31, 2001. All of the options expire on March 1, 2010 and have a price of \$2.50 per share.

All issued options under the 1987 Stock Awards Plan are vested and exercisable. 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, 1999	35,086		\$35.49
Forfeited	(5,084)	(41.77)	
Outstanding awards at December 31, 1999	30,002		34.66
Exercised	-	0.00	
Forfeited	(1,250)	(30.00)	
Outstanding awards at December 31, 2000	28,752		37.38
Forfeited	(2,750)	(23.52)	
Outstanding awards of December 31, 2001	26,002		\$46.18

</TABLE>

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 11 - STOCK OPTION PLANS - Continued

All options outstanding were exercisable at each year end.

Further information regarding options outstanding and exercisable under the 1987 Stock Awards Plan at December 31, 2001 is summarized below:

<TABLE>  
<CAPTION>

	Weighted average		
Range of exercise prices	Number of shares	Remaining life	Exercise price
<S>	<C>	<C>	<C>
\$17.50 - \$24.00	11,378	3.0	\$17.50
\$35.00 - \$64.40	7,750	1.7	41.98
\$78.80 - \$102.60	6,874	1.0	98.71
	26,002		

</TABLE>

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 12 - INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

<TABLE>  
<CAPTION>

	2001	2000	1999
<S>	<C>	<C>	<C>
Income taxes at U.S. statutory rate	\$(2,049,000)	\$(1,846,000)	\$(1,124,000)
Change in valuation allowance	1,897,000	(24,000)	15,000
Items not deductible	8,000	46,000	101,000
Expiration of net operating loss and general business credit carryforwards, net of revisions	144,000	1,824,000	1,008,000

Total tax expense	\$	-	\$	-	\$	-
-------------------	----	---	----	---	----	---

</TABLE>

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

<TABLE>  
<CAPTION>

	December 31,		
	2001	2000	1999
	<C>	<C>	<C>
Deferred tax assets (liabilities)			
Net operating loss carryforwards	\$19,259,000	\$18,491,000	\$18,438,000
General business credit carryforwards	1,396,000	445,000	456,000
Property, equipment and goodwill	154,000	(24,000)	42,000
Gross deferred tax assets	20,809,000	18,912,000	18,936,000
Valuation allowance	(20,809,000)	(18,912,000)	(18,936,000)
Net deferred taxes	\$ -	\$ -	\$ -

</TABLE>

At December 31, 2001, we had approximately \$56,442,000 of net operating loss carryforwards and approximately \$1,396,000 of general business credit carryforwards. These carryforwards expire as follows:

<TABLE>  
<CAPTION>

	Net Operating Loss Carryforwards	General Business Credit Carryforwards
	<C>	<C>
2002	\$5,448,000	\$242,000
2003	7,145,000	-
2004	5,713,000	-
2005	2,897,000	26,000
2006	198,000	38,000
Thereafter	35,243,000	1,090,000
	\$56,644,000	\$1,396,000

</TABLE>

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.

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Access Pharmaceuticals, Inc. and Subsidiaries  
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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 13 - CONTINGENCIES

Our products will require clinical trials, U.S. Food and Drug Administration approval, or approval of similar authorities internationally and acceptance in the marketplace after commercialization. Although we believe our patents and patent applications are valid, the invalidation of any of our major patents could have a material adverse effect upon our business. We compete with specialized biotechnology companies and major pharmaceutical companies, many of these competitors have substantially greater



resources than us.

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

#### NOTE 14 - QUARTERLY FINANCIAL DATA (UNAUDITED)

Our results of operations by quarter for the years ended December 31, 2001 and 2000 were as follows (in thousands, except per share amounts):

<TABLE>  
<CAPTION>

	2001 Quarter Ended			
	March 31	June 30	September 30	December 31
<S>	<C>	<C>	<C>	<C>
Revenue	\$ 211	\$ 10	\$ 11	\$ 11
Operating loss	(1,330)	(1,584)	(1,844)	(1,550)
Net loss	\$(1,171)	\$(1,517)	\$(1,744)	\$(1,595)
Basic and diluted loss per common share	\$(0.09)	\$(0.12)	\$(0.13)	\$(0.12)

</TABLE>

<TABLE>  
<CAPTION>

	2000 Quarter Ended			
	March 31	June 30	September 30	December 31
<S>	<C>	<C>	<C>	<C>
Revenue	\$ -	\$ -	\$ -	\$ 107
Operating loss	(1,100)	(1,668)	(1,493)	(1,797)
Net loss	\$(1,080)	\$(1,446)	\$(1,310)	\$(1,592)
Basic and diluted loss per common share	\$(0.14)	\$(0.13)	\$(0.11)	\$(0.11)

</TABLE>

#### NOTE 14 - SUBSEQUENT EVENT (UNAUDITED)

In February 2002, our newly created wholly owned subsidiary, Access Pharmaceuticals Australia Pty. Limited acquired the targeted therapeutic technology business of Biotech Australia Pty. Ltd.

Under the terms of the acquisition 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. \$500,000 was paid at closing, a total of up to \$525,000 will be paid over a three-year period, up to \$350,00 may be payable if events occur that result in certain new agreements and 172,584 shares of our common stock and 25,000 warrants to purchase our common stock at an exercise price of \$5.00 per share will be issued. The stock consideration to be paid is subject to restriction and cannot be sold until February 27, 2003.

The three patented targeted therapeutic technologies acquired 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.

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Access Pharmaceuticals, Inc. and Subsidiaries  
(a development stage company)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2001

NOTE 14 - SUBSEQUENT EVENT (UNAUDITED) - continued

In addition, we acquired an internal capability to perform biological studies which we previously out-sourced. We expect that this capability will enhance our ability to identify lead compounds more rapidly and develop the necessary preclinical data for regulatory filings. This acquisition is a step towards the achievement of the critical mass necessary for us to accelerate the development of our technology platforms.

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EXHIBIT 10.25

ACCESS PHARMACEUTICALS, INC.

1995 Stock Option Plan

Amendment

Access Pharmaceuticals, Inc. (the "Company"), pursuant to authority reserved in Section 21 of the 1995 Stock Option Plan of the Company, as amended (the "1995 Plan"), hereby amends the 1995 Plan as follows:

Effective as of May 21, 2001, Section 10.1 of the 1995 Plan is deleted in its entirety and is replaced with the following:

10.1. Automatic Grants. On the date of each Annual Meeting of the Stockholders of Company, each Non-Employee Director (as defined below) serving as such on such date shall receive a Nonstatutory Option for the purchase of 10,000 shares of Stock. On the date that a Non-Employee Director is initially elected or appointed by the Board of Directors such Non-Employee Director shall receive a Nonstatutory Option to purchase 20,000 shares of Stock.

IN WITNESS WHEREOF, the Company has adopted this Amendment as of the 21st day of May, 2001.

ACCESS PHARMACEUTICALS, INC.

By: /s/ Kerry P. Gray

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Kerry P. Gray

President and Chief Executive Officer

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 Certified Public Accountants

We have issued our report dated February 22, 2002, accompanying the consolidated financial statements included in the Annual Report of Access Pharmaceuticals, Inc. on Form 10-K for the year ended December 31, 2001. We hereby consent to the incorporation by reference of said report in the Registration Statements of Access Pharmaceuticals, Inc. on Form S-3 (File No. 333-37786, File No. 333-52030, File No. 333-95413 and File No. 333-64904) and on Form S-8 (File No. 33-10626, File No. 33-41134, File No. 333-45646 and 333-75136).

/s/ Grant Thornton LLP

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Grant Thornton LLP

Dallas, Texas  
March 28, 2002

SUPPLEMENTAL LEASE AGREEMENT

This Supplemental Lease Agreement is made and entered into this 20th day of September 2001 by and between:

Landlord  
POLLOCK REALTY CORPORATION  
c/o TIG Real Estate Services, Inc.  
P. O. Box 802047  
Dallas, Texas 75380-2047

and

Tenant  
Access Pharmaceuticals, Inc.  
2600 N. Stemmons Freeway, Suite 164-176  
Dallas, TX 75207-2107

This Supplemental Lease Agreement shall modify the original Lease Agreement between Pollock Realty Corporation (Landlord), and Access Pharmaceuticals, Inc. (Tenant) dated on or about July 25, 1996 and amended on February 9, 2001 in which certain real estate and premises therein described and situated in the County of Dallas, City of Dallas and the State of Texas were demised and leased by Landlord to Tenant.

It is the sole intent of this Supplemental Lease Agreement to modify the Original Lease Agreement by the following provisions:

1. Landlord and Tenant hereby agree that effective September 15, 2001 The Premises shall include Suites 162-176 and the rentable square footage contained in the Premises is deemed to be 14,468 net rentable square feet and the rentable square footage of the Building is deemed to be 39,733 net rentable square feet and Tenant's proportionate share of the Building is 36.41%
2. Beginning on the September 15, 2001 the monthly base rental as referenced in Paragraph 2.A. of the original Lease Agreement shall be as follows:

<TABLE>

<CAPTION>

Dates	Base Rent
-----	-----
<S>	<C>
9/15/01-3/31/02	\$10,836.38
4/1/02-9/30/02	\$10,933.75
10/1/02-3/31/03	\$12,116.95
4/1/03-3/31/04	\$12,237.52
4/1/04-3/31/05	\$12,358.08
4/1/05-3/31/06	\$12,478.65

</TABLE>

3. Landlord will provide \$42,000.00 for the construction of the improvements to Suite 162. All improvements shall be performed according to Landlord's specifications and shall include all costs for architecture/space planning.
4. Landlord and Tenant hereby agree that the terms and provisions of this Agreement are subject to and conditioned upon receipt by Landlord of an executed Lease Agreement from Arena Pharmaceuticals, Inc. in a form acceptable to Landlord, with respect to the Demised Premises.
5. If during the term of this Lease, any of the immediately Adjacent Premises known as Suite 160 and Suite 180 (hereinafter referred to as the "Adjacent Premises"), shall become available for lease to third parties, and provided that Tenant is not in default hereunder and has not assigned this Lease or sublet the Premises (or part hereof), Tenant shall have the first right and option to lease

the Adjacent Premises subject to the rights of other Tenants in the Building. When the Adjacent Premises becomes available, Landlord shall first offer in writing any such Adjacent Premises to Tenant upon the terms and conditions as would be offered by Landlord to third parties. If within ten (10) days after Landlord delivers Tenant such written offer, Landlord does not receive notice in writing that Tenant elects to lease the Adjacent Premises and within twenty (20) days thereafter Tenant does not execute an expansion agreement acceptable to Landlord then Tenant's right to lease the Adjacent Premises shall be waived and Tenant shall have no further rights pursuant to this Paragraph 5.

6. Landlord and Tenant represent each to the other that it has full right and authority to enter in to this Supplemental Lease Agreement.

Except as expressly provided herein all of the other terms and conditions of the Lease shall remain in effect and unchanged.

SIGNED BY THE LANDLORD, this 20th day of September, 2001.

POLLOCK REALTY CORPORATION

BY: /s/ Richard R. Pollock  
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PRINTED NAME: Richard R. Pollock  
TITLE: Vice President  
ADDRESS: C/O TIG REAL ESTATE SERVICES, INC.  
P.O. BOX 802047  
DALLAS, TEXAS 75280-2047  
PHONE: 972-661-0232  
FAX: 972-661-0235

SIGNED BY TENANT, this 18th day of September, 2001.

ACCESS PHARMACEUTICALS, INC.

BY: /s/ Kerry P. Gray  
-----

PRINTED NAME: Kerry P. Gray  
TITLE: President and CEO  
ADDRESS: 2600 STEMMONS FREEWAY  
SUITE 176  
DALLAS, TEXAS 75204-2107  
PHONE: 214-905-5100  
FAX: 214-905-5101