

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

FORM 10-K

/X/ Annual Report pursuant to Section 13 or 15(d) of the Securities  
Exchange Act of 1934 for the fiscal year ended December 31, 2000  
or

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

Commission File Number 0-9314

ACCESS PHARMACEUTICALS, INC.  
(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports  
required to be filed by Section 13 or 15(d) of the Securities Exchange Act  
of 1934 during the preceding 12 months (or for such shorter period that the  
registrant was required to file such reports) and (2) has been subject to such  
filing requirements for the past 90 days. Yes  P 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 29, 2001 was approximately  
\$27,757,000.

As of March 29, 2001 there were 12,850,478 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 2001 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 five technology platforms: synthetic polymers, bioerodible hydrogels, Residerm™, carbohydrate targeting technology, and agents for the prevention and treatment of viral disease, including HIV. In addition, our partner, GlaxoSmithKline (formerly Block Drug Company) is marketing in the United States Aphthasol R, a drug jointly developed, the first U.S. Food and Drug Administration, or FDA, FDA-approved product for the treatment of canker sores. We are developing new formulations and delivery forms to evaluate this product in additional clinical indications. We have licensed certain of the rights to amlexanox for the treatment of canker sores from GlaxoSmithKline for certain countries excluding the U.S. and the worldwide rights for certain additional indications including mucositis and oral diseases in certain territories.

Access was founded in 1974 as Chemex Corporation, a Wyoming corporation, and in 1983 changed its name to Chemex Pharmaceuticals, Inc. Chemex changed its state of incorporation from Wyoming to Delaware on June 30, 1989. In connection with the merger of Access Pharmaceuticals, Inc., a Texas corporation, with and into Chemex on January 25, 1996, we 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.

We are an emerging pharmaceutical company developing drug delivery systems and advanced polymer technology for application in cancer treatment, dermatology and oral diseases. In addition, we have developed a drug to treat canker sores that was sold to GlaxoSmithKline and which GlaxoSmithKline currently is marketing in the United States under the name Aphthasol™, subject to a royalty agreement with us. Our lead compounds and the potential markets for those compounds are as follows.

#### Marketed Product

##### Amlexanox 5% Paste (Aphthasol™)

This product 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, on August 18, 1998 we executed a license agreement for the United Kingdom and Ireland with Strakan Limited, or Strakan, to license amlexanox for the treatment of canker sores. Under the terms of this agreement, Strakan is responsible for and will bear all costs associated with the regulatory approval process for amlexanox in the United Kingdom and the European Union, will pay milestones based on cumulative sales revenue and will pay a royalty on sales of amlexanox. Strakan has filed a product license application for amlexanox 5% paste for treatment of canker sores with regulatory authorities in the United Kingdom. We anticipate that the amlexanox 5% paste product will be registered throughout Europe in the second quarter of 2001.

An international outlicensing program for amlexanox is ongoing. In addition to the 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 Aphera, Registered Mark, or R, in Canada to Paladin Labs Inc.

#### Products in Development Status

##### Polymer Platinite (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.

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.

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 third quarter of 2001. The initial Phase I study protocol is designed

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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.

We also have gained extensive experience and have intellectual property, including both issued patents and applications, protecting the use of polymers to deliver platinum compounds. Oxaliplatin which was initially approved in France and in Europe in 1999 for the treatment of colorectal cancer is now generating sales of approximately \$150 million annually. Carboplatin and Cisplatin, the most widely prescribed drug, are not indicated for the treatment of colorectal cancer which is a significant market opportunity as there are over 500,000 new cases in the developed world annually. We have commenced the development of a 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 are proceeding to develop numerous formulations with the objective of maximizing the therapeutic benefit of the clinical development candidate.

#### 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.

The OraDisc TM formulation is potentially 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.

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 and generated 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. The full statistical analysis of this study has not been completed. Additional efficacy parameters, including the measurement of ulcer size and the subjective evaluation of pain by patients will be evaluated.

A second Phase III study evaluating the ability of OraDisc TM to prevent the onset of the ulcerative phase of the disease is 80% enrolled with completion of enrollment anticipated within the next 60 days.

Utilizing this technology, we anticipate that higher drug concentrations will be achieved at the disease site increasing the effectiveness of the product.

#### OraRinse TM (Amlexanox)

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 and developed a Phase II protocol developed 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. This study commenced in the first quarter of 2000. Over 90% of head and neck cancer patients treated with radiation and chemotherapy experience mucositis. We plan to enroll 56 patients in the initial study which is being performed at multiple sites throughout the United States. This study was planned to provide the necessary information to design the Phase III clinical protocols and determine the appropriate primary

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clinical endpoint to be evaluated in such studies. Results of this study will direct the future clinical development plans for OraRinse TM.

On February 26, 2001, we announced preliminary interim data on the Phase II randomized clinical study. This interim analysis was performed to provide us with the necessary information to plan for future development activities of OraRinse TM. Due to this being an assessment of only 23 evaluable patients, at this juncture, the interim analysis did not disclose a statistically significant difference between the two arms of the study at any point in time.

In comparison to published historical data on mucositis, the mucoadhesive vehicle arm of the study provided interesting results. The surprise finding of the interim analysis was that 4 of the 11 evaluable patients receiving this novel mucoadhesive vehicle had only minimal evidence of mucositis (a score less than 0.5 on a scale of 0-5) at any time during their course of treatment. We have taken the necessary actions to file the appropriate patents to protect this technology. In addition to having protected the active ingredient in the study drug, we filed a patent to cover the use of this mucoadhesive vehicle, incorporating a drug or independent of a drug, for the treatment of radiation and chemotherapy - induced mucositis and as an oral drug delivery system for mucosal disorders.

The final patient in the trial was to be enrolled in March 2001, which should enable us to report the final data on this study in May 2001.

#### Amlexanox Cream

Studies support the concept that allergen exposure may be linked to the clinical expression of atopic dermatitis. Amlexanox is a potent anti-allergic compound. Our product is a nonsteroidal approach to the treatment of atopic dermatitis which afflicts infants and children where steroid use is often not recommended. This atopic dermatitis condition is prevalent in three percent of the adult population and 10% of the pediatric population.

A Phase I irritancy and sensitization study is scheduled to commence in the first quarter 2001. A pilot Phase II study is scheduled for the third quarter 2001.

#### Amlexanox Gel

In conjunction with the University of Kentucky we have developed an aqueous based mucoadhesive gel. Alcohol based products cause local irritation and stinging which is undesirable for the indications being evaluated. We plan to evaluate this formulation for the treatment of oral lichen planus, a chronic condition afflicting up to 2% of the population, which would project a potential \$100 million market in the U.S. Potential product advantages include reduced pain, enhanced healing and reduced disease re-occurrence rates.

An IND was filed in March 2001 and we anticipate the pilot Phase II study will start in the second quarter 2001.

#### 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.

The first zinc drug that we are developing, in conjunction with Strakan, our licensing partner, is zinc clindamycin for the treatment of acne. Topical acne drugs constitute an approximately \$750 million per year market and clindamycin is a widely prescribed drug for the treatment of acne. We believe that the addition of zinc potentially could increase the effectiveness of clindamycin through the reservoir effect of zinc, the activity of zinc and clindamycin, the improved stability of the product and the potential for zinc to overcome certain bacterial resistance.

A Phase III study of Zindaclin™ (Residerm R A gel) was completed in November 2000. The study was designed to determine whether Zindaclin™ is equally effective compared to treatment with the market leading clindamycin containing product. The primary clinical endpoint of the study, which was the change in total facial inflammatory lesion counts from the baseline visit to the end of 16 weeks of treatment, was achieved. Also, Zindaclin™ applied once a day was as effective as Dalacin R T topical lotion used twice daily. Zindaclin™ was well tolerated in the

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study. A pharmacokinetics study that was conducted indicated that at equal clindamycin dosing, 30-50% less clindamycin was absorbed into the bloodstream from the application of Zindaclin™ than from the compared application of the market leading clindamycin product.

Strakan filed a Product License Application in the United Kingdom with the Medicines Control Agency for Zindaclin™ in December 2000. We believe Zindaclin™, the first product developed utilizing the ResiDerm™ technology, could provide a broad development platform for improved delivery of many topically applied products.

We have entered into a license agreement with Strakan relating to our zinc technology. Strakan has agreed to fund the development costs of zinc clindamycin and any additional compounds developed utilizing the zinc patent, and 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. Strakan signed a Letter of Intent in August 2000, for an Option and License Agreement with Healthpoint, Ltd., which would grant a license to Healthpoint for rights to both ResiDerm™ A and the ResiDerm™ technology for the U.S., Canada, Mexico and the Caribbean.

#### Bioerodeable Hydrogel Technology

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.

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

#### 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.

#### Other Technology

We own additional patented advanced polymer technologies designed to deliver drug in response to specific diseases or take advantage of biological mechanisms. These technologies are designed to provide our next advanced drug delivery product development candidates.

#### 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

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agents which exploit our zinc patent and the University of Missouri for polymer research. 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 and plan to outlicense to, or co-develop with, marketing partners our current product candidates to finance the later clinical development phases.

We will continue to expand our internal core capabilities of chemistry, formulation, analytical methods development, clinical development 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.

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 of effective drug delivery is to control and optimize the localized release of 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 Soluble Polymer Drug Delivery Technology
- \* Topical Delivery Technology
- \* Bioerodeable Hydrogels
- \* Carbohydrate Polymer Drug Delivery Technology

Each of these platforms is discussed below:

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#### Synthetic Soluble Polymer 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 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.

#### 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, 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.

#### Bioerodeable Hydrogels

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 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, the Access 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 gel. By selecting linkers with appropriate

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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 this technology.

#### Carbohydrate Polymer 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.

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

<TABLE>

<CAPTION>

#### ACCESS DRUG PORTFOLIO

#### Clinical

Compound	Originator	Indication	FDA Filing	Stage (1)
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Cancer

- - - - -

<S> <C> <C> <C> <C>  
Polymer Platinate (AP5280) (2) Access Anti-tumor Development Phase I

Polymer Platinate (AP5286) (2) Access Colorectal Development Pre-Clinical  
cancer

OraRinse TM Amlexanox (3) Takeda Mucositis IND Phase II

Topical Delivery

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Amlexanox (4) Takeda Oral ulcers NDA Approved

OraDisc TM Amlexanox (4)  
Biodegradable Polymer Disc Takeda Oral ulcers IND Phase III

Residerm R A  
Zinc Compound (5) Access Acne CTX (9) PLA  
filed (10)

Amlexanox Cream (6) Takeda Atopic Development Phase I  
Dermatitis

Amlexanox Gel (6) Takeda Oral Lichen IND Pre-Clinical  
Planus

Antiviral

- - - - -

Anti viral compound (7) (8) NIH HIV Development Pre-Clinical

Anti viral compound (8) Rockefeller HTLV type I Development Pre-Clinical  
and II

</TABLE>

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

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

(3) Licensed from GlaxoSmithKline subject to milestone payments.

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

(5) Licensed to Strakan.

(6) Licensed from GlaxoSmithKline subject to royalty and milestone  
payments.

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

(8) Licensed from The Rockefeller University

(9) United Kingdom ("U.K.") equivalent of an IND.

(10) Filed Product License Application in the U.K. with the Medicines  
Control Agency.

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 these formulations.

Once the product candidate has been successfully screened in pilot testing, our scientists, together with external consultants, assist in designing and performing the necessary preclinical efficacy, pharmacokinetic and toxicology studies required for IND submission. External investigators and scaleup manufacturing facilities are selected in conjunction with our consultants. 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.

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 \$4,007,000, \$1,608,000 and \$1,756,000 on research and development during the years 2000, 1999 and 1998, 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. 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 acquired in 1998 the license to one U.S. and one European patent application for polymer platinum compounds. This patent and application are the result of a collaboration with The School of Pharmacy, University of London, from which the technology has been licensed. This patent and application includes a synthetic polymer, hydroxypropylmethacrylamide incorporating platينات, that can be used to exploit enhanced permeability and retention in tumors and control drug release. This patent and application 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 application also include methods for improving the pharmaceutical properties of platinum compounds. Recently additional patent applications have been filed to cover additional discoveries related to the linking of polymers to platinum compounds.

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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.

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.

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. Twelve patents have issued commencing in 1990, ten U.S. and two 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.

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 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. 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 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 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 Pharmacia 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 Nexstar

(acquired by Gilead Sciences), The Liposome Company (acquired by Elan Corporation) and

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Sequus Pharmaceuticals (acquired by Alza Corporation), are the major competing intravenous drug delivery formulations which deliver similar drug substances. 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.

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. Residerm A, which is the first product being developed utilizing the Residerm R technology, would 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.

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 28, 2001, we had 16 full time employees, seven 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.

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#### 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 \$31.9 million through December 31, 2000. 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 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 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 have product liability insurance for drug

candidates that are undergoing human clinical trials. Product 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.

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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:

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- \* 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 Access is either the owner or licensee of technology to 13 U.S. patents and to 3 U.S. patent applications now pending, and 5 European and 7 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.

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

Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.), Richard B. Stone and Howard P. Milstein currently beneficially own approximately 9.1%, 6.2% and 5.8% respectively, of our issued and outstanding common stock.

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

Provisions of our Certificate of Incorporation and By-laws 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.

#### 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.

## ITEM 2. PROPERTIES

We maintain one facility of approximately 12,000 square feet for administrative offices and laboratories in Dallas, Texas. We have a lease agreement for the facility, which terminates in March 2005. However, we have an option for early termination. Adjacent space is available for expansion which we believe would accommodate growth for the foreseeable future.

## 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 2000 and 1999. 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, 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
Fiscal Year Ended December 31, 1999		
First quarter	\$ 3.63	\$ 2.27
Second quarter	4.06	1.88
Third quarter	2.31	1.44
Fourth quarter	2.38	1.25

</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 29, 2001 was approximately 4,200. On March 29, 2001, the closing price for the common stock as quoted on the AMEX was \$2.75. There were 12,850,478 shares of common stock outstanding at March 29, 2001.

#### 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, 2000, has been derived from the audited consolidated financial statements of Access and notes thereto appearing elsewhere herein 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,				
	2000	1999	1998	1997	1996
<S>	<C>	<C>	<C>	<C>	<C>
Consolidated Statement of Operations Data:					
Total revenues	\$ 107	\$ 15	\$ -	\$ 435	\$ 167
Operating loss	(6,058)	(3,364)	(3,433)	(4,524)	(11,613)
Interest and miscellaneous income	972	53	58	119	196
Interest expense	342	12	22	36	45
Net loss	(5,428)	(3,308)	(3,397)	(4,441)	(11,462)

#### Common Stock Data:

Net loss per basic and diluted common share					
	\$ (0.49)	\$ (0.72)	\$ (1.28)	\$ (2.80)	\$ (7.68)
Weighted average basic and diluted common shares outstanding					
	11,042	4,611	2,650	1,584	1,492

	December 31,				
	2000	1999	1998	1997	1996
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short term investments					
	\$25,809	\$ 869	\$ 1,487	\$ 438	\$ 4,428
Total assets	30,526	4,600	2,351	1,447	4,928
Deferred revenue	551	155	-	-	110
Convertible notes	13,530	-	-	-	-
Total liabilities	15,522	986	556	848	868
Total stockholders' equity	\$15,004	\$ 3,614	\$ 1,795	\$ 599	\$ 4,060

</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 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. 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 the Company 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 assumption of \$239,000 in trade and accrued payables and \$184,000 of Tacora's capital lease obligations. Certain milestones were met up to June 30, 2000 and an aggregate of 6,752 shares of our common stock were issued to certain former liability holders of Tacora as a result. There are no further milestones to be met. The aggregate purchase price has been allocated to the net assets acquired

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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 were incorporated in Wyoming in 1974 as Chemex Corporation, and in 1983 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. and changed our name to Access Pharmaceuticals, Inc. We have proprietary patents or rights to five technology platforms: synthetic polymers, bioerodible hydrogels, Residerm™, carbohydrate targeting technology and agents for the prevention and treatment of viral disease, including HIV. In addition, our partner GlaxoSmithKline, formerly Block Drug Company, is marketing in the United States a product named Aphthasol R, a drug jointly developed, the first FDA approved product for the treatment of canker sores. We are developing new formulations and delivery forms to evaluate this product in additional clinical indications. We have licensed certain of the rights for amlexanox from GlaxoSmithKline for certain countries excluding the U.S. and the worldwide rights for certain additional indications including mucositis and oral diseases in certain territories.

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, 2000, our accumulated deficit was \$31,881,000, of which \$8,894,000 was the result of the write-off of excess purchase price.

##### Recent Developments

We filed an IND with the FDA and developed a Phase II protocol developed 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. This study commenced in the first quarter of 2000. Over 90% of head and neck cancer patients treated with radiation and chemotherapy experience mucositis. We plan to enroll 56 patients in the initial study which is being performed at multiple sites throughout the United States. This study was planned to provide the necessary information to design the Phase III clinical protocols and determine the appropriate primary clinical endpoint to be evaluated in such studies. Results of this study will direct the future clinical development plans for OraRinse TM.

On February 26, 2001, we announced preliminary interim data on the Phase II randomized clinical study. This interim analysis was performed to provide us with the necessary information to plan for future development activities. Due to this being an assessment of only 23 evaluable patients, at this juncture, the interim analysis did not disclose a statistically significant difference between the two arms of the study at any point in time.

In comparison to published historical data on mucositis, the mucoadhesive vehicle arm of the study provided interesting results. The surprise finding of the interim analysis was that 4 of the 11 evaluable patients receiving this novel mucoadhesive vehicle had only minimal evidence of mucositis (a score less than 0.5 on a scale of 0-5) at any time during their course of treatment. We have taken the necessary actions to file the appropriate patents to protect this technology. In addition to having protected the active ingredient in the study drug, we filed a patent to cover the use of this mucoadhesive vehicle, incorporating a drug or independent of a drug, for the treatment of radiation and chemotherapy - induced mucositis and as an oral drug delivery system for mucosal disorders.

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An IND was filed with the FDA 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. The full statistical analysis of this study has not been completed. Additional efficacy parameters, including the measurement of ulcer size and the subjective evaluation of pain by patients will be evaluated.

A Phase III study of Zindaclin TM (Residerm R A gel) was completed in November 2000. The study was designed to determine whether Zindaclin TM is equally effective compared to treatment with the market leading clindamycin containing product. The primary clinical endpoint of the study, which was the change in total facial inflammatory lesion counts from the baseline visit to the end of 16 weeks of treatment, was achieved. Also, Zindaclin TM applied once a day was as effective as Dalacin R T topical lotion used twice daily. Zindaclin TM was well tolerated in the study. A pharmacokinetics study conducted indicated that at equal clindamycin dosing 30-50% less clindamycin was absorbed into the bloodstream compared to the market leading clindamycin product.

Strakan filed a Product License Application in the United Kingdom with the Medicines Control Agency for Zindaclin TM in December 2000. We believe Zindaclin TM, the first product developed utilizing the ResiDerm TM technology, could provide a broad development platform for improved delivery of many topically applied products.

Strakan, our UK and Ireland marketing partner, 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. This will provide a major marketing opportunity to expand usage of the product and to attract sufferers of canker sores to contact medical practitioners to request the product.



## Other Developments

On November 30, 2000, we completed a voluntary odd-lot stock buy-back program through which stockholders who owned 25 or fewer shares of our common stock, or Small-lot Stockholders, were able to elect to tender their shares for sale to Access. Under this program, we repurchased the shares held by Small-lot Stockholders who validly tendered their shares pursuant to the terms of the odd-lot stock buy-back program. We purchased 819 shares at a total cost of \$3,500.

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 are not convertible for the first twelve months. The note pays 7.0% interest per annum for the first twelve months and if not converted at that time the notes will be adjusted to 7.7% interest per annum. The notes are due September 13, 2005.

In addition, on September 13, 2000 we completed a transaction offering 250,000 shares of treasury stock to an individual at \$5.50 share. We received gross proceeds of \$1.4 million from this sale.

We initiated a Phase I study to determine the dosing levels of the Polmer Platinante, AP5280, in September 2000. AP5280, is a chemotherapeutic agent incorporating platinum bound to a polymer designed to improve the clinical benefit of platinum therapy in cancer patients by concentrating the drug in the tumor and reducing the side effects. The study is expected to be completed in the third quarter 2001, depending on the number of patients required to determine maximum dosing levels.

During the second quarter of 2000 we completed two self-managed private placement sales of our common stock, pursuant to which we sold 250,000 and 507,750 shares of our common stock at per share prices of \$3.00 and \$5.00, respectively. We received gross proceeds of \$3.3 million from these sales. In addition, on March 1, 2000, with the assistance of an investment bank, we completed the closing of a separate 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. In accordance with the offering terms of this \$12.0 million private placement, the placement agent for the offering received warrants to purchase 382,315 shares of our common stock at \$2.50 per share, and elected to receive

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520,905 shares of common stock in lieu of certain sales commissions. The funds from the private placements will be used principally for general corporate purposes to support our operations and to fund clinical development of our portfolio of product candidates.

On March 28, 2000, our application for listing on the American Stock Exchange, or AMEX, was approved and we began trading on AMEX on March 30, 2000 under the symbol AKC.

On February 25, 2000 we signed licensing agreements with Mipharm S.p.A. Pursuant to these agreements, we granted to Mipharm marketing and manufacturing rights for amlexanox for numerous indications including the prevention and treatment of canker sores and mucositis, oral lichen planus and atopic dermatitis. We also granted manufacturing rights for Europe to Mipharm for the products covered by the agreements. These licensing agreements cover Italy, Switzerland, Turkey and Lebanon and relate to:

- \* the 5% paste formulation, approved in the United States for the treatment of canker sores, which is in the regulatory process in Europe;
- \* the OraDisc R formulation which just completed a Phase III clinical study for the prevention and treatment of canker sores;
- \* OraRinse R which is in Phase II clinical evaluation for the prevention and treatment of mucositis;
- \* the 5% amlexanox cream formulation for the treatment for atopic dermatitis which is scheduled to commence a Phase I irritancy and sensitization study in the first quarter 2001; and

\* a 5% amlexanox gel for the treatment of oral lichen planus for which a pilot Phase II study will start in the second quarter 2001.

Mipharm also has the option to license other Access product developments in the fields of Dermatology and Gynecology in the territory covered by the license agreements. In addition, under the terms of the agreements, Mipharm paid up-front licensing fees and will make milestone payments and Access will receive a percentage of the product sales made in the territory. Moreover, pursuant to an investment agreement with Mipharm, Mipharm made equity investments in Access in August 2000 and February 2001 and has the right to make an additional equity investments in Access up to February 2002.

#### Liquidity and Capital Resources

As of March 29, 2001 our principal source of liquidity is \$24,845,000 of cash and cash equivalents. Working capital as of December 31, 2000 was \$24,397,000, representing a increase in working capital of \$24,309,000 as compared to the working capital as of December 31, 1999 of \$88,000. The increase in working capital at December 31, 2000 was due to the funds received from our March, May and September private placements, our September 2000 issuance of convertible notes and licensing revenues.

Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of December 31, 2000 of \$31,881,000. We have funded our operations primarily through private sales of common stock and convertible notes. Contract research payments, licensing fees and milestone payments from corporate alliances and mergers have also provided funding for operations.

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. We expect that our existing capital resources will be adequate to fund our current level of operations through the year 2003.

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;
- \* the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;

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- \* 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.

#### Results of Operations

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

Revenue in 2000 was \$107,000, as compared to \$15,000 in 1999, an increase of \$92,000. Licensing revenue is recognized over the period of the performance obligation. Licensing revenue recognized in 2000 is from

several agreements. Revenues in 1999 were for an option payment on our carbohydrate polymer technology as applied to the field of selectively replicating viruses.

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, 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);

- \* higher development costs for our new hydrogel project (\$72,000);

- \* additional travel expenses (\$52,000)

- \* moving expenses for scientific personal (\$56,000); and

- \* recruitment expenses (\$59,000).

We expect research spending to increase and remain higher than 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.

Total general and administrative expenses were \$1,736,000 for 2000 and \$1,471,000 in 1999. 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

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- \* 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 is due to:

- \* additional amortization of goodwill of \$143,000 recorded in 2000 versus 1999 as a result of the purchase 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.

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

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.

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.

#### Comparison of Years Ended December 31, 1999 and 1998

We had \$15,000 in revenues for 1999 as compared to no revenues in 1998. 1999 revenues were for a twelve month option payment on our carbohydrate polymer drug technology as applied to the field of selectively replicating viruses.

Total research spending for 1999 was \$1,608,000 as compared to \$1,756,000 for the same period in 1998, a decrease of \$148,000. The decrease in expenses was due to:

- \* \$354,000 less external development costs due to the completion of university research contracts in 1998.

This decrease was partially offset by the following increases:

- \* \$94,000 for scientific consulting costs;

- \* \$64,000 for salary and related costs;

- \* \$40,000 for clinical development costs, and

- \* other net increases totaling \$8,000.

General and administrative expenses were \$1,471,000 for 1999, an increase of \$7,000 as compared to the same period in 1998. The increase was primarily due to the following:

- \* \$249,000 increased business consulting expense due to the issuance of warrants issued in connection with consulting agreements;

- \* \$41,000 additional shareholder expenses due primarily to increased investor relation expenses; and

- \* other net increases totaling \$17,000.

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These increases were partially offset by a reduction of:

- \* \$119,000 in patent expenses due to the filing of four patents and the prosecution of European patents in 1998 compared with one patent filing in 1999;

- \* \$81,000 in salary and related expenses due primarily to our Vice President of Business Development leaving in the third quarter of 1998 and not being replaced;

- \* \$69,000 in other professional costs; and

- \* \$31,000 in travel and entertainment expenses.

Depreciation and amortization for 1999 was \$285,000 as compared to \$213,000 for the same period in 1998, an increase of \$72,000. The increase in amortization is due to amortization of goodwill of \$103,000 recorded as a result of the purchase of Virologix Corporation offset by lower depreciation reflecting that some major assets have been fully depreciated.

Interest income decreased to \$53,000 in 1999 from \$58,000 in 1998 due to lower average cash balances in 1999. Interest expense decreased to \$12,000 in 1999 from \$22,000 in 1998 due to lower average obligations under capital leases during 1999.

Accordingly, these expenses resulted in a loss for the twelve months ended December 31, 1999 of \$3,308,000, or a \$0.72 basic and diluted loss per common share compared with a loss of \$3,397,000, or a \$1.28 basic and diluted loss per common share for the twelve months ended December 31, 1998.

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

We invest our excess cash and short-term investments in certificates of deposit, corporate securities with high quality ratings, and U.S. government securities. These investments are not held for trading or other speculative purposes. These financial investment securities all mature in 2001 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 \$70,000. The estimated effect assumes no changes in our short-term investments at December 31, 2000. We do not believe that we are exposed to any market risks, as defined. We are not exposed to risks for changes in foreign currency exchange rates, 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.

### 26 PART III

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

The information requested by this item will be contained in the Company's definitive Proxy Statement ("Proxy Statement") for its 2001 Annual Meeting of Stockholders to be held on May 21, 2001 and is incorporated herein by reference. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days subsequent to December 31, 2000.

#### ITEM 11. EXECUTIVE COMPENSATION

The information requested by this item will be contained in the Company's definitive Proxy Statement and is incorporated herein by reference. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days subsequent to December 31, 2000.

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information requested by this item will be contained in the Company's definitive Proxy Statement and is incorporated herein by reference. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days subsequent to December 31, 2000.

#### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information requested by this item will be contained in the Company's definitive Proxy Statement and is incorporated herein by reference. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days subsequent to December 31, 2000.

### 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 Grant Thornton LLP	F-1
Consolidated Balance Sheets at December 31, 2000 and 1999	F-2
Consolidated Statements of Operations for 2000, 1999 and 1998 and the period from February 24, 1988 (Inception) to December 31, 2000	F-3
Consolidated Statements of Stockholders' Equity (Deficit) for the period from February 24, 1988 (Inception) to December 31, 2000	F-4
Consolidated Statements of Cash Flows for 2000, 1999 and 1998 and the period from February 24, 1988 (Inception) to December 31, 2000	F-7
Notes to Consolidated Financial Statements	F-8

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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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)

2.2 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)

2.3 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)

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.

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 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)

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 10Q for the quarter ended March 31, 1998)

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3.0 Exhibits (continued)

Exhibit Number

10.11 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 10Q for the quarter ended June 30, 1998)

\*10.12 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)

10.13 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)

10.14 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)

\*10.15 Employment Agreement of David P. Nowotnik, Ph.D  
(Incorporated by reference to Exhibit 10.19 of our Form 10K for the year ended December 31, 1999)

\*10.16 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10K for the year ended December 31, 1999)

\*10.17 2000 Special Stock Option Plan and Agreement (Incorporated by reference to Exhibit 10.24 of our Form 10Q for the quarter ended September 30, 2000)

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

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

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

ACCESS PHARMACEUTICALS, INC.

Date March 29, 2001 By: /s/ Kerry P. Gray

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Kerry P. Gray  
President and Chief Executive  
Officer

Date March 29, 2001 By: /s/ Stephen B. Thompson

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

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

Date March 29, 2001 By: /s/ Kerry P. Gray

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Kerry P. Gray  
President and Chief Executive  
Officer, Director

Date March 29, 2001 By: /s/ J. Michael Flinn

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J. Michael Flinn, Director

Date March 29, 2001 By: /s/ Stephen B. Howell

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Stephen B. Howell, Director





Short term investments, at cost	17,394,000	-
Accounts receivable	251,000	88,000
Accrued interest receivable	196,000	-
Prepaid expenses and other current assets	133,000	117,000
	-----	-----
Total current assets	26,389,000	1,074,000
Property and equipment, net	116,000	108,000
Debt issuance costs	861,000	-
Licenses, net	887,000	899,000
Investments, at cost	150,000	150,000
Goodwill, net	2,115,000	2,361,000
Other assets	8,000	8,000
	-----	-----
Total assets	<u>\$30,526,000</u>	<u>\$4,600,000</u>

#### LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities		
Accounts payable and accrued expenses	1,158,000	805,000
Accrued interest payable	283,000	-
Deferred revenues	551,000	155,000
Current portion of obligations under capital leases	-	26,000
	-----	-----
Total current liabilities	1,992,000	986,000
Convertible notes	13,530,000	-
	-----	-----
Total liabilities	15,522,000	986,000
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, 12,844,699 at December 31, 2000 and 6,089,762 at December 31, 1999	132,000	61,000
Additional paid-in capital	47,802,000	30,006,000
Notes receivable from stockholders	(1,045,000)	-
Treasury stock, at cost - 819 shares at December 31, 2000	(4,000)	-
Deficit accumulated during the development stage	(31,881,000)	(26,453,000)
	-----	-----
Total stockholders' equity	15,004,000	3,614,000
	-----	-----
Total liabilities and stockholders' equity	<u>\$30,526,000</u>	<u>\$4,600,000</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			
	2000	1999	1998	December 31, 2000
<S>	<C>	<C>	<C>	<C>
Revenues				
Research and development		\$ -	\$ -	\$ - \$ 2,711,000
Option income		- 15,000	-	- 2,164,000
Licensing revenues		107,000	-	- 432,000
Total revenues		107,000	15,000	- 5,307,000
Expenses				
Research and development		4,007,000	1,608,000	1,756,000 15,980,000
General and administrative		1,736,000	1,471,000	1,464,000 11,661,000
Depreciation and amortization		422,000	285,000	213,000 1,976,000
Write-off of excess purchase price		-	-	- 8,894,000
Total expenses		6,165,000	3,364,000	3,433,000 38,511,000
Loss from operations		(6,058,000)	(3,349,000)	(3,433,000) (33,204,000)
Other income (expense)				
Interest and miscellaneous income		972,000	53,000	58,000 1,857,000
Interest expense		(342,000)	(12,000)	(22,000) (534,000)
		630,000	41,000	36,000 1,323,000
Net loss		\$(5,428,000)	\$(3,308,000)	\$(3,397,000) \$(31,881,000)
Basic and diluted loss per common share		\$ (0.49)	\$ (0.72)	\$ (1.28)
Weighted average basic and diluted common shares outstanding		11,042,141	4,611,315	2,650,168

</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 (DEFICIT)

<TABLE>  
<CAPTION>

	Common stock		Note		Deficit	
	Shares	Amount	paid-in capital	Additional from stockholders	receivable from Treasury stock	accumulated during the development stage
<S>	<C>	<C>	<C>	<C>	<C>	<C>
Balance, February 24, 1998		- \$	- \$	- \$	- \$	- \$
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)



Net loss for the year	-	-	-	-	-	(4,441,000)
-----						
Balance, December 31, 1997	1,630,000	16,000	20,331,000	-	-	(19,748,000)
Common stock issued, \$3.00 per share, net of costs of \$405,000	1,795,000	18,000	4,538,000	-	-	-
Common stock issued, for nil proceeds	4,000	-	-	-	-	-
Warrants issued at \$4.00 per share for financial consulting services	-	-	37,000	-	-	-
Net loss for the year	-	-	-	-	-	(3,397,000)
-----						
Balance, December 31, 1998	3,429,000	34,000	24,906,000	-	-	(23,145,000)
Common stock issued, \$2.00 per share, net of costs of \$271,000	1,658,000	17,000	2,814,000	-	-	-

</TABLE>

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

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) - CONTINUED

<TABLE>

<CAPTION>

	Common stock Shares	Common stock Amount	Note Additional paid-in capital	Deficit accumulated receivable from Treasury stockholders	Deficit accumulated during the development stage	
	<C>	<C>	<C>	<C>	<C>	<C>
Common stock issued, Virologix Corporation merger, \$2.00 per share	1,000,000	10,000	1,990,000	-	-	-
Common stock issued, for nil proceeds	3,000	-	-	-	-	-
Warrants issued at \$3.00 and \$2.93 per share for financial consulting services	-	-	296,000	-	-	-
Net loss for the year	-	-	-	-	-	(3,308,000)
-----						
Balance, December 31, 1999	6,090,000	61,000	30,006,000	-	-	(26,453,000)
Common stock issued, \$2.50 per share, net of costs \$1,214,000	5,354,000	54,000	11,992,000	-	-	-
Common stock issued, \$3.00 per share	250,000	2,000	748,000	-	-	-
Common stock issued, \$5.00 per share	508,000	5,000	2,534,000	-	-	-
Common stock issued to investors for cash exercise of warrants (from \$2.50 to \$3.00 per share)	65,000	1,000	172,000	-	-	-
Common stock issued to investors for cashless exercise of warrants	152,000	2,000	(2,000)	-	-	-
Common stock issued to directors and consultants for cash exercise of options and SARs (from \$0.00 to \$3.00 per share)	50,000	-	126,000	-	-	-
Common stock issued, \$3.50 per share	143,000	1,000	498,000	-	-	-
Common stock issued to officers, \$5.50 per share	190,000	2,000	1,043,000	(1,045,000)	-	-
Common stock issued for nil proceeds	43,000	4,000	(4,000)	-	-	-
Purchase common stock \$3.00 share	-	-	-	(750,000)	-	-
Purchase common stock \$2.50 to \$7.94	-	-	-	(4,000)	-	-
Sale of treasury stock \$5.50 per share	-	-	625,000	-	750,000	-
Warrants issued at \$2.00 and \$3.00 per share for financial consulting services	-	-	64,000	-	-	-

Net loss for the year	-	-	-	-	-	(5,428,000)
Balance, December 31, 2000	12,845,000	\$132,000	\$47,802,000	\$(1,045,000)	\$(4,000)	\$(31,881,000)

</TABLE>

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			
	Year ended December 31,			inception to
	2000	1999	1998	December 31,
	2000	1999	1998	2000
<S>	<C>	<C>	<C>	<C>
Cash flows from operating activities:				
Net loss	\$(5,428,000)	\$(3,308,000)	\$(3,397,000)	\$(31,881,000)
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	64,000	296,000	37,000	929,000
Research expenses related to common stock granted	-	-	-	100,000
Depreciation and amortization	422,000	285,000	213,000	1,976,000
Amortization of debt costs	54,000	-	-	54,000
Deferred revenue	396,000	155,000	-	441,000
Licenses	(100,000)	(425,000)	-	(525,000)
Change in operating assets and liabilities:				
Accounts receivable	(163,000)	(88,000)	1,000	(252,000)
Accrued interest receivable	(196,000)	-	-	(196,000)
Prepaid expenses and other current assets	(16,000)	(63,000)	(3,000)	(134,000)
Other assets	-	-	2,000	(6,000)
Accounts payable and accrued expenses	353,000	(97,000)	(92,000)	396,000
Accrued interest payable	283,000	-	-	283,000
Net cash used in operating activities	(4,331,000)	(3,245,000)	(3,239,000)	(19,921,000)
Cash flows from investing activities:				
Capital expenditures	(72,000)	(5,000)	(4,000)	(1,245,000)
Sales of capital equipment	-	-	9,000	15,000
Purchases of short-term investments and certificates of deposit	(17,394,000)	-	-	(17,394,000)
Purchase of businesses, net of cash acquired	-	(102,000)	-	(226,000)
Other investing activities	-	-	(100,000)	(150,000)
Net cash used in investing activities	(17,466,000)	(107,000)	(95,000)	(19,000,000)
Cash flows from financing activities:				
Proceeds from notes payable	-	-	-	721,000
Payments of principal on obligations under capital leases	(26,000)	(97,000)	(173,000)	(750,000)
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	18,553,000	2,831,000	4,556,000	34,962,000
Net cash provided by financing activities	29,343,000	2,734,000	4,383,000	47,336,000
Net increase (decrease) in cash				

and cash equivalents	7,546,000	(618,000)	1,049,000	8,415,000
Cash and cash equivalents at beginning of period	869,000	1,487,000	438,000	-
	-----	-----	-----	
Cash and cash equivalents at end of period	\$ 8,415,000	\$ 869,000	\$ 1,487,000	\$ 8,415,000
	=====	=====	=====	=====
Cash paid for interest	\$ 50,000	\$ 12,000	\$ 22,000	\$ 239,000
Cash paid for income taxes	-	-	-	-
Supplemental disclosure of noncash transactions				
Payable accrued for fixed asset purchase	\$ -	\$ -	\$ -	\$ 47,000
Elimination of note payable to Chemex				
Pharmaceuticals due to merger	-	-	-	100,000
Stock issued for license on patents	-	-	-	500,000
Equipment purchases financed through capital leases	-	-	-	82,000
Net liabilities assumed in acquisition of Tacora Corporation	-	-	-	455,000
Acquisition of Virologix Corporation				
Assets acquired including goodwill	-	2,571,000	-	2,571,000
Liabilities assumed	-	(469,000)	-	(469,000)
Stock issued	-	(2,000,000)	-	(2,000,000)

</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, 2000

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.

Certain amounts have been reclassified to conform with current period classification.

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, 2000

#### 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. 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, 2000

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

##### Use of Estimates

We have made a number of estimates and assumptions relative to the reporting of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities to prepare these consolidated financial statements in conformity with generally accepted accounting principles. Actual results could differ from those estimates.

##### 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. On January 1, 1996, we 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 securities.

##### New Accounting Pronouncements

The Financial Accounting Standards Board has issued Statements of Financial Accounting Standards No. 133 and 138, regarding derivative financial instruments which are required to be adopted in years beginning after June 15, 2000. Because our minimal use of derivatives, we do not anticipate that the adoption of the new Statement will have a significant effect on earnings or on the financial position of the Company.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2000

NOTE 2 - FINANCIAL INSTRUMENTS

The following is a summary of available-for-sale securities:

<TABLE>  
<CAPTION>

	Cost	Estimated Fair Value
<S>	<C>	<C>
U.S. government securities	\$ 4,579	\$ 4,579
Certificates of deposit	12,815	12,815
Commercial paper	7,008	7,008
Total	\$ 24,402	\$ 24,402

</TABLE>

Included in cash equivalents at December 31, 2000 are \$7,008 of commercial paper. All securities have maturities of less than one year.

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.

Pro forma disclosure relating to the Virologix acquisition reflects our operating results combined with the operating results of Virologix:

\* for the year ended December 31, 1999 as if the Virologix acquisition occurred on January 1, 1999, and

\* for the year ended December 31, 1998 as if the Virologix acquisition occurred on January 1, 1998.

This pro forma information does not purport to be indicative of what would have occurred had the acquisition been made as of those dates, or of results which may occur in the future.

<TABLE>  
<CAPTION>

	For the year ended December 31,	
	1999	1998
<S>	<C>	<C>
Total revenue	\$ -	\$ -
Net loss	\$(3,565,000)	\$(4,175,000)

Net loss per common share       \$ (0.59) \$ (0.79)

</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, 2000

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 Expense	
	Fees	Reimbursement
<S>	<C>	<C>
2000	\$ 72,000	\$ 1,000
1999	72,000	9,000
1998	72,000	11,000

</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 Expense		Exercise	
	Fees	Reimbursement	Warrants	Price
<S>	<C>	<C>	<C>	<C>
2000	\$ 66,000	\$ 9,000	30,000	\$ 2.00
1999	62,000	18,000	30,000	\$ 3.00
1998	8,000	4,000	-	-

</TABLE>

Richard B. Stone, a former Director who resigned on February 16, 2001, is a managing director of Sunrise Securities Corp., which acted as a placement agent in the private placements of our common stock. Mr. Stone received the following shares and warrants:

<TABLE>

<CAPTION>

Year	Shares	Exercise	
		Warrants	Price
<S>	<C>	<C>	<C>
2000	83,434	101,995	\$2.50
1999	101,225	86,499	\$2.00
1998	109,904	98,474	\$3.00

</TABLE>

Preston Tsao, a Director, is Managing Director for Corporate Finance of Sunrise Securities Corp., which acted as a placement agent in the private placements of our common stock. Mr. Tsao received the following shares and warrants:

<TABLE>

<CAPTION>

Year	Shares	Exercise	
		Warrants	Price

<S>	<C>	<C>	<C>
2000	1,436	65,791	\$2.50
1999	-	15,310	\$2.00
1998	-	11,015	\$3.00

Until August 1, 2001, Sunrise has the right to designate one individual for election to our board of directors and, if Sunrise exercises their right, we are required to use our best efforts to cause their nominee to be elected. In addition, if Sunrise does not exercise their right, we shall permit a representative of Sunrise to attend and observe all board of directors meetings.

We have a "Patent Purchase Agreement" dated April 5, 1994, as amended on January 23, 1996, with Dr. David F. Ranney, a shareholder. Under terms of the agreement, Dr. Ranney was entitled to yearly cash royalty payments as consideration for the assignment of patents to us. As of May 31, 1998, Dr. Ranney signed an agreement whereby all rights, title and interest in and to all inventions and confidential information became our sole and exclusive property.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2000

NOTE 5 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

<TABLE>  
<CAPTION>

	December 31,	
	2000	1999
<S>	<C>	<C>
Laboratory equipment	\$ 848,000	\$ 808,000
Laboratory and building improvements	50,000	31,000
Furniture and equipment	190,000	177,000
	1,088,000	1,016,000
Less accumulated depreciation and amortization	972,000	908,000
Net property and equipment	\$ 116,000	\$ 108,000

</TABLE>

Depreciation and amortization on property and equipment was \$64,000, \$121,000, and \$166,000 for the years ended December 31, 2000, 1999 and 1998, 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 (\$10,500 in 2001 and 2000 and \$10,000 in 1999) 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

\$22,000 in 2000 and \$13,000 in 1999.

#### NOTE 7 - 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 are not convertible for the first twelve months. The note pays 7.0% interest per annum for the first twelve months and if not converted at that time the notes will be adjusted to 7.7% interest per annum. The notes are due September 13, 2005. Total expenses of issuance were \$915,000 and are amortized over the life of the notes.

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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED Three years ended December 31, 2000

#### NOTE 8 - COMMITMENTS

At December 31, 2000, Access does not have any capital lease obligations. We do have commitments under noncancelable operating leases as follows:

<TABLE>  
<CAPTION>

	Operating leases -----
<S>	<C>
2001	\$ 118,000
2002	121,000
2003	122,000
2004	120,000
2005	121,000
Thereafter	30,000
	-----
Total future minimum lease payments	\$ 632,000 =====

</TABLE>

We lease certain office and research and development facilities under an operating lease. Rent expense for the years ended December 31, 2000, 1999 and 1998 was \$85,000, \$81,000 and \$77,000, respectively.

#### NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT)

##### 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. On July 20, 1999, our wholly-owned subsidiary Access Holdings, Inc. merged with and into Virologix Corporation, a Delaware corporation. 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.

#### Restricted Stock Purchase Program

On October 12, 2000, the Board of Directors authorized a Restricted Stock Purchase Program. Under the Program, the Company's executive officers and corporate secretary were given the opportunity to purchase shares of common stock in an individually designated amount per participant determined by the Compensation Committee of the Board of Directors. A total of 190,000 shares were purchased under the Program by four eligible participants at \$5.50 per share, the fair market value of the common stock on October 12, 2000, for an aggregate consideration of \$1,045,000. The purchase price was paid through the participant's delivery of a 50%-recourse promissory note payable to the Company for three

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

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED Three years ended December 31, 2000

#### NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT) - Continued

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 receivables 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 four years.

#### Warrants

There were warrants to purchase a total of 1,073,072 shares of common stock outstanding at December 31, 2000. All the warrants were exercisable at December 31, 2000. The warrants had various prices and terms as follows:

<TABLE>  
<CAPTION>

Summary of Warrants	Warrants Outstanding	Exercise Price	Expiration Date
<S>	<C>	<C>	<C>
2000 offering (a)	372,616	\$ 2.00	3/01/05
2000 scientific consultant (b)	30,000	2.00	1/01/07
2000 scientific consultant (c)	7,500	3.00	1/01/04
1999 offering (d)	120,858	2.00	10/18/04
1999 warrants assumed in merger (e)	27,145	12.98	4/30/02
1999 financial advisor (f)	100,000	2.93	3/26/04
1999 scientific consultant (g)	30,000	3.00	1/01/03
1998 offering (h)	325,658	3.00	7/30/03
1998 financial advisor (i)	15,000	4.00	12/01/03
1997 financial advisor (j)	37,500	7.50/9.00	6/30/02
1995 lease/buyback (k)	6,795	3.00	9/21/01
Total	1,073,072		

</TABLE>

a) 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 per share and expire five years from date of issuance.

b) 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.

c) 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.

d) 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.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2000

NOTE 9 - STOCKHOLDERS' EQUITY (DEFICIT) - Continued

e) 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 and expire between March 24, 2002 and November 1, 2002.

f) 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.

g) 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.

h) 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. Unexercised warrants at

December 31, 2000 are 325,658.

i) 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.

j) 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.

k) We also have warrants outstanding to purchase 6,795 shares of common stock at \$3.00 per share. These warrants expire in September 2001.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2000

NOTE 10 - 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"). Options granted under 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, 2000, there were 873,416 additional shares available for grant under the 1995 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. The option vests ratably over a four year period and is exercisable over a ten-year period from the date of grant. The option was granted with an exercise price equal to the market value at the date of grant.

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 its 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:

<TABLE>  
<CAPTION>

	December 31,		
	2000	1999	1998
<S> Net loss	<C>	<C>	<C>



As reported	\$(5,428,000)	\$(3,308,000)	\$(3,397,000)
Pro forma	(6,366,000)	(3,603,000)	(3,583,000)

Basic and diluted loss per share

As reported	(\$.49)	(\$.72)	(\$1.28)
Pro forma	(\$.57)	(\$.78)	(\$1.35)

</TABLE>

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 2000, 1999 and 1998, respectively: dividend yield of 0% for all periods; volatility of 118%, 91% and 122%; risk-free interest rates of 4.85%, 6.62% and 4.84% and expected lives of four years for all periods. The weighted average fair values of options granted were \$2.88, \$1.37 and \$2.40 per share during 2000, 1999 and 1998, respectively.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2000

NOTE 10 - STOCK OPTION PLANS - Continued

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, 1998	32,150	\$ 20.40	
Granted	306,500	3.00	
Forfeited	(32,150)	(20.40)	
	-----		
Outstanding options at December 31, 1998	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	
Exercisable at December 31, 1998	142,500	3.00	
Exercisable at December 31, 1999	300,875	2.66	
Exercisable at December 31, 2000	414,239	2.59	

</TABLE>

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2000 is summarized below:

<TABLE>

<CAPTION>

	Weighted average Number of shares	Weighted Number of average exercise price	Weighted Number of average exercise price
	-----	-----	-----
Range of exercise prices	Remaining life in years	Exercise price	exercisable price
-----	-----	-----	-----

<S>	<C>	<C>	<C>	<C>	<C>
\$2.00	304,000	9.0	\$2.00	187,198	\$2.00
\$2.50	149,500	10.0	2.50	-	-
\$2.94 - 3.563	300,084	8.2	3.04	227,041	3.04
\$5.50 - 7.8125	373,000	10.0	6.03	-	-
	-----		-----		
	1,126,584		414,239		
	=====		=====		

</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, 2000

NOTE 10 - STOCK OPTION PLANS - Continued

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

<TABLE>  
<CAPTION>

	Shares	Weighted- average exercise price		
<S>	<C>	<C>		
Outstanding options at January 1, 2000			-	
Granted	500,000	\$5.50		
	-----			
Outstanding options at December 31, 2000			500,000	\$5.50
	=====			

</TABLE>

None of the options in the 2000 Special Stock Option Plan were exercisable at December 31, 2000. All of the options have a remaining life of 10 years at \$5.50 per share.

Summarized information for the 1987 Stock Awards Plan is as follows:

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, 1998			43,989	\$38.00
Forfeited	(8,903)	(47.75)		
	-----			
Outstanding awards at December 31, 1998			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

</TABLE>

All options outstanding were exercisable at each year end.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED  
Three years ended December 31, 2000

NOTE 10 - STOCK OPTION PLANS - Continued

Further information regarding options outstanding and exercisable under the 1987 Stock Awards Plan at December 31, 2000 is summarized below:

<TABLE>  
<CAPTION>

Range of exercise prices	Weighted average		
	Number of shares	Remaining life	Exercise price
<S>	<C>	<C>	<C>
\$17.50 - \$24.00	14,128	3.4	\$18.77
\$35.00 - \$64.40	7,750	2.7	41.98
\$78.80 - \$102.60	6,874	2.0	98.71
	28,752		

</TABLE>

NOTE 11 - INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

<TABLE>  
<CAPTION>

	2000	1999	1998
<S>	<C>	<C>	<C>
Income taxes at U.S. statutory rate	\$(1,846,000)	\$(1,124,000)	\$(1,155,000)
Change in valuation allowance	(24,000)	15,000	1,142,000
Items not deductible for tax	46,000	101,000	13,000
Expiration of net operating loss and general business credit carryforwards	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,		
2000	1999	1998

<S>	<C>	<C>	<C>
Deferred tax assets (liabilities)			
Net operating loss carryforwards	\$18,491,000	\$18,438,000	\$17,101,000
General business credit carryforwards	445,000	456,000	443,000
Property, equipment and goodwill	(24,000)	42,000	24,000
	-----	-----	-----
Gross deferred tax assets	18,912,000	18,936,000	17,568,000
Valuation allowance	(18,912,000)	(18,936,000)	(17,568,000)
	-----	-----	-----
Net deferred taxes	\$ -	\$ -	\$ -
	=====	=====	=====

</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, 2000

NOTE 11 - INCOME TAXES - Continued

During 2000, our gross deferred tax asset decreased by \$24,000 due expiration of net operating loss carryforwards less the effect of the net loss. The valuation allowance decreased by a corresponding amount.

At December 31, 2000, we had approximately \$54,385,000 of net operating loss carryforwards and approximately \$445,000 of general business credit carryforwards. These carryforwards expire as follows:

2001	\$ 3,190,000
2002	5,690,000
2003	7,171,000
2004	5,751,000
2005	5,364,000
Thereafter	27,664,000
	-----
	\$ 54,830,000

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

NOTE 12 - 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.

EXHIBIT 21

Subsidiaries of the Registrant

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 23, 2001, accompanying the consolidated financial statements included in the Annual Report of Access Pharmaceuticals, Inc. on Form 10-K for the year ended December 31, 2000. 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 and File No. 333-95413) and on Form S-8 (File No. 33-10626, File No. 33-41134 and File No. 333-45646).

/s/ Grant Thornton LLP

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Grant Thornton LLP

Dallas, Texas  
March 30, 2001