#### 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, 1998

Commission File Number 0-9314

## ACCESS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	83-02215	17
(State of Incorporation)	(I.R.S. Em	ployer I.D. No.)
2600 Stemmons Freeway, Suite 176,	Dallas, TX	75207
(Address of Principal Executive Offi	ces)	(Zip Code)

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

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

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

Common Stock, One Cent (\$0.01) Par Value

(Title of Class)

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

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

The aggregate market value of the outstanding voting stock held by non-affiliates of the registrant as of March 25, 1999 was approximately \$7,242,000.

As of March 25, 1999 there were 3,429,402 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 1999 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 - FINANCIAL INFORMATION

ITEM 1. BUSINESS

#### Overview of Current Operations

Access Pharmaceuticals, Inc. (together with its subsidiary, "Access" or the "Company") was founded in 1974 as Chemex Corporation, a Wyoming corporation, and in 1983 changed its name to Chemex Pharmaceuticals, Inc. ("Chemex"). 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 ("API"), with and into the Company on January 25, 1996 (the "Merger"), the name of the Company was changed to Access Pharmaceuticals, Inc.

Access' principal executive office is at 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207; its telephone number is (214) 905-5100.

#### Recent Developments

On March 1, 1999, the Company and a wholly owned subsidiary of the Company entered into a merger agreement with Virologix Corporation ("Virologix"), whereby Virologix will become a wholly owned subsidiary of the Company. The closing of the merger is subject to certain conditions, including the condition that the Company raise at least \$3.0 million in equity financing.

Virologix is a privately held company focused on the development of product candidates for the prevention and treatment of viral diseases, including HIV. Under the terms of the agreement, the Virologix shareholders will receive 1,000,000 shares of common stock of the Company. It is anticipated that the closing of the acquisition will take place during the second quarter of 1999.

#### Business

Access is a drug delivery company using advanced polymer technology for application in cancer treatment, dermatology and medical imaging. In addition, the Company has developed a drug to treat canker sores that was sold to Block Drug Company ("Block") and is currently being marketed in the United States by Block, subject to a royalty agreement with the Company. The Company's lead compounds are as follows:

Amlexanox - This is currently the only compound approved by the Food and Drug Administration ("FDA") for the treatment of canker sores. Independent market research sponsored by the Company 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.

In 1995, Access sold its rights to amlexanox to Block subject to a retained royalty. On June 8, 1998, the Company entered into an agreement to license back from Block these rights to amlexanox for certain international markets. Pursuant to the new agreement, the Company announced on August 18, 1998 that it signed a License Agreement for the United Kingdom and Ireland with Strakan Limited ("Strakan") to license amlexanox for the treatment of canker sores. Under the terms of this agreement, Strakan will be responsible for and will bear all costs associated with the regulatory approval process in the United Kingdom and European Union, will pay milestones based on cumulative sales revenue and will pay a royalty on sales. The Company also announced that Strakan had filed the product license application for amlexanox 5% paste with UK regulatory authorities. It is anticipated that the product will be registered throughout Europe in 1999. An international outlicensing program is ongoing.

The Company recently signed a license agreement with Block 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 effects an estimated 400,000 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 Company believes amlexanox could have a clinical benefit in treating and preventing this condition because of the clinical similarities of mucositis to canker sores for which amlexanox has proven efficacy. An Investigational New Drug ("IND") has been filed with the FDA and a Phase II protocol developed to

investigate a mouthwash formulation for the prevention and treatment of mucositis in cancer patients undergoing treatment.

1

Access, in conjunction with Atrix Laboratories, Inc., is working to develop additional formulations including a mucoadhesive disc and a mucoadhesive gel that can also be adapted to an aerosol spray. These formulations will be clinically investigated in the prevention of canker sores, oral lichen planus and mucositis.

Polymer Platinate (AP 5070) - 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, and is increasingly used as an adjunct to radiation and surgery, to improve efficacy, and is used as the primary therapy for some solid tumors and metastases. The current optimal strategy for chemotherapy involves exposing patients to the most intensive cytotoxic regimens they can tolerate. Clinicians attempt to design a combination of drugs, dosing schedule and method of administration to increase the probability that cancerous cells will be destroyed while minimizing the harm to healthy cells.

For chemotherapeutic agents to be effective in treating cancer patients, the agent must reach the target cells in effective quantities with minimal toxicity in normal tissues. Most current drugs have significant limitations. Certain cancers are inherently unresponsive to chemotherapeutic agents, while other cancers initially respond, but subgroups of cancer cells acquire resistance to the drug during the course of therapy, with the resistant cells surviving and resulting in relapse. Another limitation of current anti-cancer drugs is that serious toxicity, including bone marrow suppression or irreversible cardiotoxicity, can prevent their administration in curative doses.

Polymer Platinate is a chemotherapeutic agent which the Company believes has the potential to have significantly superior efficacy in treating numerous cancers compared to existing platinum compounds. 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. The Company's Polymer Platinate (as to which the Company has applied for patents) seeks to achieve this goal by attaching a large polymer to a small platinum molecule. This takes advantage of the fact that the cells lining the walls of blood vessels that feed tumors are usually leaky or hyperpermeable, allowing the large Polymer Platinate molecule to enter the tumor in preference to other tissue, which does not have leaky or hyperpermeable blood vessels. On the other hand, 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 (EPR). In addition, the polymer is designed to shield the platinum from interactions with normal cells while the drug is in circulation, thereby reducing toxicity. The proposed mechanism of how Polymer Platinate is taken up by tumor cells bypasses known membraneassociated mechanisms for development of tumor resistance, a common cause of failure of chemo-therapeutic drugs over the course of treatment.

In animal models, the Company's Polymer Platinate has delivered up to 63 times the amount of Platinum to tumors compared with cisplatin (the standard platinum formulation) at the maximum tolerated dose, and the Company's Polymer Platinate was approximately 2.5 times more effective in inhibiting tumor growth than cisplatin alone. In terms of dosing, in animal studies, up to 15 times more platinum has been injected using the Company's Polymer Platinate, 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 drug to the tumor.

The Company plans to commence human clinical trials for its Polymer Platinate if the results of additional ongoing activities are successful.

Zinc Clindamycin - The complexing of zinc to a drug has the effect of enhancing the penetration of the drug into the skin, yet holding the drug in the skin. This phenomenon is called the "reservoir effect," and it makes zinc potentially effective for the delivery of dermatological drugs. The Company has a broad patent covering the use of zinc for such purposes. The first zinc drug being developed by Access, in conjunction with its licensing partner, is Zinc Clindamycin for the treatment of acne. Acne drugs constitute an approximately \$700 million per year market. Clindamycin is a widely prescribed drug for the treatment of acne, and Access believes that the addition of zinc could potentially significantly increase the effectiveness of the drug 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.

#### 2

The Company believes that its zinc technology could provide a broad development platform for improved delivery of many topically applied products. The Company is currently evaluating zinc complexed with vitamin D, retanoids and anti-fungals.

Access has entered into a license agreement with Strakan relating to its zinc technology. Strakan has agreed to fund the development costs of Zinc Clindamycin and any additional compounds developed utilizing the zinc patent, and will share equally in all milestone payments received from the sublicensing of the compound. In addition, Access will receive a royalty on sales of products based on this technology.

MRI Imaging Agent - Magnetic resonance imaging (MRI) is a nonradioactive method of producing imaging for the diagnosis of a broad range of diseases and conditions. To date, for the diagnosis of cancer, the sensitivity of MRI has been insufficient to pick up very small tumors. The Company is developing an imaging agent that may greatly enhance the ability of MRI to detect certain small tumors. Currently, gadolinium, a rare earth metal, is used as an imaging agent in MRI, but its use is restricted to imaging brain tumors and vasculature. The reason why gadolinium is not used for other parts of the body is that approved gadolinium agents alone defuse much too rapidly throughout the body and are eliminated very quickly. The Access imaging agent consists of gadolinium attached to a polymer that selectively binds to tumors. Animal studies have indicated that the use of this imaging agent can result in up to 40% brighter images and the ability to detect tumors significantly smaller than those detectable with currently available techniques. In addition, in animal studies, the imaging agent has increased by up to four times the amount of time during which images can be taken, and this increased time period would represent a major potential advantage in handling patients.

Access has a license agreement with The Dow Chemical Company ("Dow Chemical") to use Dow Chemical's technology to develop binding agents of sufficient purity for human clinical use.

Access owns additional patented advanced technologies designed to deliver drug in response to specific diseases or take advantage of biological mechanisms. These technologies are designed to provide the Company's next advanced drug delivery product development candidates.

## Drug Development Strategy

A part of Access' integrated drug development strategy is to form creative alliances with centers of excellence in order to obtain alternative lead compounds while minimizing overall cost of research. Access has signed agreements with The School of Pharmacy, University of London for platinate polymer technology, Dow Chemical for metal binding technology to develop imaging agents and radiopharmaceuticals, Strakan for the delivery of topical therapeutic agents which exploit the Access zinc patent, Duke University for advanced drug delivery systems and Atrix Laboratories, Inc. for mucoadhesive polymer formulations of amlexanox.

The Access strategy is to initially focus on utilizing its technology in combination with approved drug substances to develop novel patentable formulations of potential therapeutic and diagnostic products. The Company believes that this will expedite product development, both preclinical and clinical, and ultimately product approval. To reduce financial risk and equity financing requirements, Access is directing its resources to the preclinical and early clinical phase of development and plans to outlicense to, or co-develop with, marketing partners its current product candidates during the clinical development phases.

Access has initiated and will continue to expand its internal core capabilities

of chemistry, formulation, analytical methods development, initial process scale up, carbohydrate analysis, drug/diagnostic targeting screens and project management capability to maximize product opportunities in a timely manner. However, the manufacturing scaleup, preclinical testing and product production will be contracted 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, Access does not currently plan to become a fully integrated pharmaceutical company.

Consequently, Access expects 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, it is believed that the Access technology can be more rapidly developed and successfully introduced into the marketplace.

> 3 around

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 nontargeted fraction. Conventional drug delivery systems such as controlled release, sustained release, transdermal systems, etc., are based on a physical erosion process 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. The Company believes that its 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 polymer carrier formulations to significantly enhance the therapeutic efficacy and reduce toxicity of a broad spectrum of products. This is achieved by utilizing Bio~Responsive TM Polymers as novel drug delivery solutions to match the specific physical properties of each drug with the biological characteristics of each disease and targeting sites of disease activity. The Company believes that the ability to achieve physiological triggering of drug release at the desired site of action could enable the Access Bio~Responsive TM Polymers to potentially have broad therapeutic applications in the site specific delivery of chemotherapeutic agents in cancer, infection, inflammation, drugs for other autoimmune diseases, proteins, peptides and gene therapy.

Bio~Responsive TM Polymers mimic the natural transport mechanisms in the body which are involved in the localized delivery of biological mediators and cellular trafficking. Access uses a multi-faceted approach through the use of both natural carbohydrates and synthetic polymers. Access' central focus is to use Bio~Responsive TM Polymer systems that can respond to normal biochemical or disease-induced signals to localize drug carrier and release drug in a highly selective fashion. These polymeric drug carriers can be applied to a wide range of drug molecules including proteins and nucleotides and can be engineered to control pharmacokinetics and body distribution, site-selectivity, site-release of drug and drug clearance from non-target sites.

Access Core Drug Delivery Technology Platforms

Access' current drug delivery technology platforms take advantage of the following biological mechanisms to improve drug delivery:

- \* disease specific carbohydrate recognition by vascular endothelial cells and underlying tissue
- \* enhanced permeability and retention in tumors

\* triggered secretion of biological mediators

## Access Carbohydrate Polymer Drug Delivery Technology

The Access 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. Access has developed glycosaminoglycan carriers to selectively image and treat diseases involving the neovascular endothelium. Access believes that its glycosaminoglycan technology has broad potential in a number of therapeutic applications including cancer, inflammation and infection.

#### Access Synthetic Soluble Polymer Drug Delivery Technology

In collaboration with The School of Pharmacy, University of London, Access has developed a number of synthetic polymers, including hydroxypropylmethacrylamide co-polymers and polyamidoamines designed to be used to exploit EPR ("enhanced permeability and retention") in tumor cells and control drug release. Many solid tumor cells possess

1

vasculature that is hyperpermeable (i.e., "leaky") to macromolecules. In addition to this enhanced permeability, tumors usually lack effective lymphatic and/or capillary drainage. Consequently they selectively accumulate circulating macromolecules (up to 10% of an intravenous dose per gram in mice). This effect has been termed EPR, and is thought to constitute the mechanism of action of SMANCS (styrene-maleic/anhydrideneocarzinostatin), which is in regular clinical use in Japan for the treatment of hepatoma. These polymers take advantage of endothelial permeability with the drug carrying polymers getting trapped in tumors and then being taken up by tumor cells. Linkages between the polymer and drug can be designed to be cleaved extracellularly or intracellularly. 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, e.g. cisplatin.

## Access Condensed Phase Smart Polymer Drug Delivery Technology

The Access condensed phase polymer system is based on the Smart Polymer Matrixes of Secretory Granules from secretory cells such as the mast cell or goblet cell. The matrix in the secretory granule of the mouse mast cell contains a negatively charged, heparin proteoglycan network which condenses in the presence of divalent cations, such as calcium and histamine, and monovalent cations, such as sodium. This matrix has a number of unique electrical and mechanical properties in response to biochemical or electrical signals. The heparin gel expands several-fold when a secretory granule fuses with a cell membrane, allowing ions from outside the cell to rush in, causing release of contents. Thus, nature has evolved a highly advanced "smart polymer" gel to control the storage and release of molecules destined for exocytosis. These ubiquitous natural mechanisms can be mimicked by engineering smart polymer matrices to deliver a wide range of molecules, including proteins and genes, in response to specific triggering stimuli. This natural mechanism provides the basis of a novel technology for releasing drugs on demand, with avoidance of systemic toxicities. Access has commenced the development of a system to mimic the secretory granule matrix to meet the biological requirement of different drugs, delivery routes and disease processes. In a unique inventive step, bioengineered, pore-forming proteins, with triggers and switches that selfassemble in membranes, can be incorporated into coated particles to control drug release. This represents a logical step in the development of the next generation of Access drug delivery technology platforms towards commercialization of systems that can trigger the release of drug, at site. in response to disease-specific signals. Initial proof of concept will focus on the triggered release of chemotherapeutic cancer and anti-inflammatory

agents and vaccines.

Access Topical Delivery Technology

Access has granted a license to Strakan for the development of compounds that utilize zinc ions to produce a reservoir of drug in the skin to increase the efficacy 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 produce a "reservoir effect" in the skin or mucous membranes. Such a reservoir effect can be produced by the complexation 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, i.e.:

- \* To increase skin or membrane residence time
- \* To decrease drug transit time
- \* 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 retarding their ability to move from the skin to the systemic circulation.

5 Research Projects, Products and Products in Development

ACCESS DRUG PORTFOLIO <TABLE> <CAPTION> Clinical Compound Originator Indication FDA Filing Stage (1) Cancer <S> <C> <C>  $\langle C \rangle$  $\langle C \rangle$ Development Pre-Clinical Polymer Platimate Access Anti-tumor AP 2011 Access MRI Contrast Agent Development Research Radiopharmaceutical Access Cancer Diagnosis Development Research Amlexanox(2)Takeda Mucositis IND Phase II Topical Delivery - ------Amlexanox(3)(CHX-3673) FDA Approved Completed Takeda Oral ulcers Zinc compound(4) Access Enhancing drug CTX (5) Phase II penetration and retention in the skin (acne) Amlexanox (6) Takeda Oral Ulcers Development Pre-Clinical Biodegradeable Polymer Disc Amlexanox (6) Takeda Oral Lichen Planus Development Pre-Clinical Mucoadhesive Gel </TABLE>

(1) See "Government Regulations" for description of clinical stages.

(2) Licensed from Block subject to milestone payments.

- (3) Sold to Block. Subject to a Royalty Agreement. International rights (except Japan and Israel) licensed from Block subject to royalty and milestone payments.
- (4) Licensed to Strakan.
- (5) United Kingdom equivalent of an IND.
- (6) Licensed from Block subject to milestone and royalty payments.

Access begins 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 the Access technology. Access has a core internal development capability with significant experience in these formulations.

Once the product candidate has been successfully screened in pilot testing, Access' 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 Company consultants. Access does not plan to have an extensive clinical development organization as this is planned to be conducted by a development partner.

With all of Access' product development candidates, there can be no assurance 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

#### 6

tested in humans. There can be no assurance that any of these projects will be successfully completed or that regulatory approval of any product will be obtained.

The Company expended approximately \$1,756,000, \$2,433,000 and \$1,405,000 on research and development during the years 1998, 1997 and 1996, respectively.

### Patents

Access believes that the value of technology both to Access and to potential corporate partners is established and enhanced by its broad intellectual property positions. Consequently, Access already has issued and seeks 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 its inventions and prospective products.

One U.S. and one European patent has issued and two European patents are pending for the use of zinc as a pharmaceutical vehicle for enhancing the penetration and retention of drug in the skin. The 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. The patents also relate to topical treatment methods including such reservoir effect enhancers and to pharmaceutical compositions containing them.

Access acquired the license to two U.S. and two PCT patent applications for polymer platinum compounds through the Tacora acquisition. These patent applications are the result of a collaboration between the Company and the School of Pharmacy, University of London, from which the technology has been licensed. The patents include a number of synthetic polymers, including hydroxypropylmethacrylamide and polyamidoamines, that can be used to exploit enhanced permeability and retention and control drug release. The patent applications include a pharmaceutical composition for use in tumor treatment comprising polymer-platinum compound through linkages which are designed to be cleaved under selected conditions to yield a platinum which accumulates at a tumor site. The patent applications also include methods for improving the pharmaceutical properties of platinum compounds.

Access, through its Tacora subsidiary, has four issued U.S. patents and one pending European patent application in condensed-phase microparticles. These patents are licensed from the Mayo Clinic and were acquired by Access through the merger with Tacora in December 1997. This technology is based on the Smart Polymer Matrices of Secretory Granules from secretory cells such as the mast cell or goblet cell. The technology has the following properties to control the storage and release of molecules within the body: 1) encapsulation of high concentration of small molecules, nucleotides and proteins; 2) highly stable storage medium for a variety of naturally occurring biological molecules; and 3) release of stored products in response to environments, external or internal signals to ensure correct location, timing and concentration of secreted products in the body.

Access holds 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. Nine patents have issued commencing in 1990 (eight U.S. and one European) and an additional four patent applications are pending (one U.S. and three European).

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 cytotaxins at sites of disease as a mechanism for selective targeting, and they claim recognized usable carrier substances which selectively bind to these induced target determinants.

Under the various license agreements with Block, Access has the worldwide rights, excluding Japan, for the use of amlexanox for the treatment of mucositis in patients undergoing chemotherapy and radiation treatment for cancer and in AIDS patients, and the worldwide rights excluding Japan, the United States and Israel for the use of amlexanox for dermatological use. Block has the rights to market any product developed for dermatological use in the U.S. and Takeda Chemical Industries, Ltd. has the rights to market any product in Japan.

#### 7

Access has a strategy of maintaining an ongoing line of continuation applications for each major category of patentable carrier and delivery technology. By this approach, Access is extending the intellectual property protection of its 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 Regulations**

Access is 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 Access' 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 Access' 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 ("GMP") 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, and the FDA approval of a New Drug Application ("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 effective 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 or 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. Hence, Access cannot with any certainty estimate how long the approval cycle may take.

Access is 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 the Company may develop and market products in the future. Most of the Company's potential competitors are large, well established pharmaceutical, chemical or health care companies with considerably greater financial, marketing, sales and technical resources than are available to the Company. Additionally, many of the Company's potential competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with the Company's product lines. The Company's potential products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be addressed by the Company's developments, technological advances affecting the cost of production, or marketing or pricing actions by one or more of the Company's potential competitors. The Company's business,

#### 8

financial condition and results of operation could be materially adversely affected by any one or more of such developments. There can be no assurance that the Company will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on the Company's 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. The Company is aware of certain development projects for products to treat or prevent certain diseases targeted by the Company. The existence of these potential products or other products or treatments of which the Company is not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed by the

## Company.

The Company believes that the principal current competitors to Access' polymer targeting technology fall into two categories: monoclonal antibodies and liposomes. Access believes that its technology potentially represents a significant advance over these older technologies because its 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. Currently, liposomal formulations being developed by Nexstar, Inc., The Liposome Company, Inc. and Sequus Pharmaceuticals, Inc. 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. Access expects that technological developments will occur at a rapid rate and that competition is likely to intensify as various alternative delivery system technologies achieve certain if not identical advantages.

Products developed from the Residerm 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 technology, would compete with products including Benzamycin, marketed by a subsidiary of Rhone-Poulenc Rorer Inc.; Cleocin-T and a generic topical clindamycin, marketed by Pharmacia & Upjohn Co, Inc.; Benzac, marketed by a subsidiary of L'Oreal; and Triaz, marketed by Medicis Pharmaceutical Corp.

Even if Access' products are fully developed and receive required regulatory approval, of which there can be no assurance, Access believes that its products can only compete successfully if marketed by a company having expertise and a strong presence in the therapeutic area. Consequently, Access does not currently plan to establish an internal marketing organization. By forming strategic alliances with major pharmaceutical and diagnostic medical imaging companies, management believes that Access' 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 1, 1999, Access had 12 full time employees, six of whom have advanced scientific degrees. Access believes that it maintains good relations with its personnel. In addition, to complement its internal expertise, Access contracts with scientific consultants, contract research organizations and university research laboratories that specialize in various aspects of drug development including toxicology, sterility testing and preclinical testing to complement its internal expertise.

#### Operations Prior to January 1996

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Access operated as Chemex prior to the Merger, which occurred on January 25, 1996. On September 14, 1995, the Chemex Stockholders approved the sale of the rights to amlexanox to Block, while retaining the right to receive royalties from future sales of amlexanox. As consideration for the sale of the Company's share of amlexanox, Block (a) made a nonrefundable up-front royalty payment of \$2.5 million; (b) is obligated to pay Access \$1.5 million as a prepaid royalty at the end of the calendar month during which Block has achieved sales of amlexanox oral products of \$25 million; and (c) after the payment of such \$1.5 million royalty, is obligated to pay royalties to Access for all sales in excess of \$45 million, as calculated pursuant to the terms of the agreement, as amended.

Risk Factors

Certain of the statements contained in this Annual Report on Form 10-K are forward looking statements within the meaning of Section 27a of the Securities Act of 1933, as amended, that involves risks and uncertainties

including but not limited to the risk factors set forth below:

History of Losses and Expectation of Future Losses; Uncertainty of Future Profitability The Company has incurred a cumulative operating loss of approximately \$23.1 million through December 31, 1998. Losses have resulted principally from costs incurred in research and development activities related to the Company's efforts to develop target candidates and from the associated administrative costs. The Company expects to incur significant additional operating losses over the next several years and expects cumulative losses to increase substantially due to expanded research and development efforts, preclinical and clinical trials and development of manufacturing capabilities. In the next few years, the Company's revenues may be limited to any amounts received under research or drug development collaborations that the Company may establish. There can be no assurance, however, that the Company will be able to establish any collaborative relationships on terms acceptable to the Company. The Company's ability to achieve significant revenue or profitability is dependent on its ability to successfully complete the development of drug candidates, to develop and obtain patent protection and regulatory approvals for the drug candidates and to manufacture and commercialize the resulting drugs. The Company may not receive revenues or royalties from commercial sales for a significant number of years, if at all. Failure to receive significant revenues or to achieve profitable operations would impair the Company's ability to sustain operations. There can be no assurance that the Company will ever successfully identify, develop, commercialize, patent, manufacture and market any additional products, obtain required regulatory approvals or achieve profitability.

Research and Development Focus Access' focus is on commercializing compounds covered by proprietary biopharmaceutical patents. Although Access may in the future have some royalty income, Access is still in the development stage, and its proposed operations are subject to all the risks inherent in the establishment of a new business enterprise, including the need for substantial capital. Access has recorded minimal revenue to date. It is anticipated that Access will remain principally engaged in research and development activities for an indeterminate, but substantial, period of time. As a nonrevenue producing company, normal credit arrangements are unavailable to Access, therefore, it is likely that Access would be forced to accept unfavorable terms if it should attempt to raise additional needed funds through borrowing. There can be no assurance that any such credit arrangement would be available. Further, it is anticipated that additional losses will be incurred in the future, and there can be no assurance that Access will ever achieve significant revenues or profits.

Uncertainties Associated with Research and Development Activities 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 the research and development effort and ultimately could have a material adverse effect on Access.

Absence of Operating Revenue Royalties received by Access for sales of Actinex TM and amlexanox have not been significant to date. There can be no assurance of revenue or profits in the future. Access currently has no products approved for sale and there can be no assurance as to the expenditures of time and resources that may be required to complete the development of potential Access products and obtain approval for sale or if such completion and approval can be realized.

Going Concern Uncertainty The Company's audited financial statements at and for the twelve months ended December 31, 1998 contain a reference to the Company's ability to continue as a going concern.

Early Stage of Product Development; No Assurance of Successful Commercialization The Company's drug candidates will be 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 the Company's drug candidates will be found to be unsafe, ineffective or toxic 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 the Company from marketing such drugs; or that third parties will market superior or equivalent drugs. The failure to develop safe, commercially viable drugs would have a material adverse effect on the Company's business, operating results and financial condition.

#### 10

Additional Financing Requirements; Uncertainty of Available Funding The Company will require substantial additional funds for its development programs, for operating expenses, for pursuing regulatory clearances, and for prosecuting and defending its intellectual property rights before it can expect to realize significant revenues from commercial sales. The Company believes that existing capital resources, interest income and revenue from possible licensing agreements and collaborative agreements, will be sufficient to fund its operating expenses and capital requirements as currently planned for four to six months. However, there can be no assurance that such funds will be sufficient to fund such operating expenses and capital requirements during such period. The Company's actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including the results of the Company's research and development and collaboration programs, the timing and results of preclinical trials, the ability of the Company to maintain existing and establish new collaborative agreements with other companies to provide funding to the Company, the technological advances and activities of competitors and other factors. Thereafter, the Company will need to raise substantial additional capital to fund its operations. The Company intends to seek such additional funding through additional equity offerings or collaborative or other arrangements with corporate partners. If additional funds are raised by issuing equity securities, further dilution to existing stockholders may result and future investors may be granted rights superior to those of existing stockholders. There can be no assurance, however, that any such equity offerings will occur, or that additional financing will be available from any of these sources or, if available, will be available on acceptable or affordable terms. If adequate funds are not available, the Company may be required to delay, reduce the scope of or eliminate one or more of its research and development programs or to obtain funds by entering into arrangements with collaborative partners or others that require the Company to issue additional equity securities or to relinquish rights to certain technologies or drug candidates that the Company would not otherwise issue or relinquish in order to continue independent operations.

Dependence on Others; Collaborations The Company's strategy for the research, development and commercialization of its potential pharmaceutical products may require the Company to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others, in addition to those already established, and may therefore be dependent upon the subsequent success of outside parties in performing their responsibilities. There can be no assurance that the Company will be able to establish additional collaborative arrangements or license agreements that the Company deems necessary or acceptable to develop and commercialize its potential pharmaceutical products, or that any of its collaborative arrangements or license agreements will be successful.

No Marketing, Sales, Clinical Testing or Regulatory Compliance Activities In view of the development stage of the Company and its research and development programs, the Company has restricted hiring to research scientists and a small administrative staff and has made no investment in manufacturing, production, marketing, product sales or regulatory compliance resources. If the Company successfully develops any commercially marketable pharmaceutical products, it may seek to enter joint venture, sublicense or other marketing arrangements with parties that have an established marketing capability or it may choose to pursue the commercialization of such products on its own. There can be no assurance, however, that the Company will be able to enter into such marketing arrangements on acceptable terms, if at all. Further, the Company will need to hire additional personnel skilled in the clinical testing and regulatory compliance process and in marketing or product sales if it develops pharmaceutical products that it commercializes itself. There can be no assurance, however, that it will be able to acquire such resources or personnel.

Manufacturing Limitations The Company intends to establish arrangements with contract manufacturers to supply sufficient quantities of products to conduct clinical trials as well as for the manufacture, packaging, labeling and distribution of finished pharmaceutical products if its potential products are approved for commercialization. If the Company is unable to contract for a sufficient supply of its potential pharmaceutical products on acceptable terms, the Company's preclinical and human clinical testing schedule may be delayed, resulting in the delay of submission of products for regulatory approval and initiation of new development programs, which may have a material adverse effect on the Company. If the Company encounters delays or difficulties in establishing relationships with manufacturers to produce. package, label and distribute its finished pharmaceutical or other medical products (if any), market introduction and subsequent sales of such products would be adversely affected. Moreover, contract manufacturers that the Company may use must adhere to current Good Manufacturing Practices ("GMP") required by the FDA. Manufacturing facilities must pass a preapproval plant inspection before the FDA will issue a pre-market approval or product and establishment licenses, where applicable, for the products. If the Company is unable to obtain or retain third party manufacturing on commercially acceptable terms, it may not be able to commercialize its products as planned. The Company's potential dependence upon third parties for the manufacture of its products may adversely affect the Company's profit margins and its ability to develop and deliver such products on a timely

11

and competitive basis. The Company has no experience in the manufacture of pharmaceutical products in clinical quantities or for commercial purposes. In addition, there can be no assurance that the Company will be able to manufacture or enter into arrangements with third parties for the manufacture of any products successfully and in a cost-effective manner.

Hazardous Materials; Environmental Matters The Company's research and development processes involve the controlled use of hazardous materials. The Company is subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such material and certain waste products. Although the Company believes that its 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, the Company could be held liable for any damages that result and such liability could exceed the resources of the Company. Although the Company believes that it is in compliance in all material respects with applicable environmental laws and regulations and currently does not expect to make material capital expenditures for environmental control facilities in the nearterm, there can be no assurance that the Company will not be required to incur significant costs to comply with environmental laws and regulations in the future, nor that the operations, business or assets of the Company will not be materially adversely affected by current or future environmental laws or regulations.

Impact of Extensive Government Regulation 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, sampling activities and other costly and time-consuming procedures to establish their safety and efficacy. All of the Company's drug candidates will require governmental approvals for commercialization, none of which have been obtained. Preclinical and clinical trials and manufacturing of the Company's 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. There can be no assurance as to when the Company, independently or with its collaborative partners, might submit an Investigational New Drug Application ("IND") for FDA or other regulatory review. Government regulation also affects the manufacturing and marketing of pharmaceutical products.

The effect of government regulation may be to delay marketing of the Company's potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon the Company's 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 the Company's marketing as well as the Company's ability to generate significant revenues from commercial sales. There can be no assurance that FDA or other regulatory approvals for any drug candidates developed by the Company 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 initial regulatory approvals for the Company's drug candidates are obtained, the Company, its drugs and its 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 such drug or manufacturer, including withdrawal of the drug from the market. The regulatory standards are applied stringently by the FDA and other regulatory authorities and failure to comply can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions and criminal prosecution.

The FDA has developed two "fast track" policies for certain new drugs (including anti-cancer agents), one policy for expedited development and review and one policy for accelerated approval. The expedited development and review policy applies to new drug therapies that are intended to treat persons with life threatening and severely debilitating illnesses, especially where no satisfactory alternative therapy exists. The accelerated approval policy applies to certain new drugs that are intended to treat person with serious or life-threatening illnesses that provide a meaningful therapeutic benefit to patients over existing treatments. See "Business-Government Regulation." There can be no assurance that any drug candidate contemplated by the Company will qualify for the FDA's various fast track or priority approval policies. Nor can there be any assurance that such policies will remain as currently implemented by the FDA.

Drug-related Risks Adverse side effects of treatment of diseases and disorders in both human and animal patients are business risks in the pharmaceutical industry. 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 cause a company to terminate its efforts to develop the drug for commercial use. Even after FDA approval of an NDA, adverse side effects may

#### 12

develop to a greater extent than anticipated during the clinical testing phase and could result in legal action against a company. Drug developers and manufacturers, including Access, may face substantial liability for damages in the event of adverse side effects or product defects identified with their products used in clinical tests or marketed to the public. There can be no assurance that Access will be able to satisfy any claims for which it may be held liable resulting from the use or misuse of products which it has developed, manufactured or sold.

Potential Product Liability and Availability of Insurance The Company's business exposes it to potential liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. The use of the Company's drug candidates in clinical trials may expose the Company to product liability claims and possible adverse publicity. The risks will expand with respect to the Company's drug candidates, if any, that receive regulatory approval for commercial sale. Product liability insurance for the biotechnology industry is generally expensive, if available at all. The Company does not have product liability insurance but intends to apply for such coverage if and when its drug candidates are tested in human clinical trials. However, such coverage is becoming increasingly expensive and there can be no assurance that the Company will be able to obtain insurance coverage at acceptable costs or in a sufficient amount, if at all, or that a product liability claim would adversely affect the Company's business, operating results or financial condition.

Reimbursement and Drug Pricing Uncertainty The successful commercialization of, and the interest of potential collaborative partners to invest in, the development of the Company's drug candidates will depend substantially on reimbursement of the costs of the resulting drugs and related treatments at acceptable levels from government authorities, private health insurers and other organizations, such as health maintenance organizations ("HMOs"). There can be no assurance that reimbursement in the United States or elsewhere will be available for any drugs the Company 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, the Company's drugs, thereby adversely affecting the Company's business. If reimbursement is not available or is available only to limited levels, there can be no assurance that the Company will be able to obtain collaborative partners to commercialize its drugs, or would be able to obtain a sufficient financial return on its own manufacture and commercialization of any future drugs.

Third-party payers are increasingly challenging the prices charged for medical products and services. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which can control or significantly influence the purchase of health care services and products, as well as legislative proposals to reform health care or reduce government insurance programs, may result in lower prices of pharmaceutical products. The cost containment measures that health care providers are instituting, including practice protocols and guidelines and clinical pathways, and the effect of any health care reform, could materially adversely affect the Company's ability to sell any of its drugs if successfully developed and approved. Moreover, the Company is unable to predict what additional legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such legislation or regulation would have on the Company's business.

Uncertainty of Patents and Proprietary Rights The Company's success will depend in part on its ability to obtain U.S. and foreign patent protection for its drug candidates and processes, preserve its trade secrets and operate without infringing the proprietary rights of third parties. Because of the length of time and expense associated with bringing new drug candidates through the development and regulatory approval process to the marketplace, the pharmaceutical industry has traditionally placed considerable importance on obtaining patent and trade secret protection for significant new technologies, products and processes. Although Access has eighteen U.S. patents and is either the owner or licensee of technology as to which there are three U.S. patent applications now pending, there can be no assurance that any additional patents will issue from any of the patent applications owned by, or licensed to, the Company. Further, there can be no assurance that any rights the Company may have under issued patents will provide the Company 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. 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. There can be no assurance that any existing or future patents issued to, or licensed by, the Company 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 the Company's drug candidates. If the Company's drug candidates or processes are found to infringe upon the patents or otherwise impermissibly utilize the intellectual property of others, the Company's development, manufacture and sale of such drug candidates could be severely restricted or prohibited. In such event, the Company may be required to obtain licenses from third parties to utilize the patents or proprietary rights of others. There can be

#### 13

no assurance that the Company will be able to obtain such licenses on acceptable terms, or at all. If the Company becomes involved in litigation regarding its intellectual property rights or the intellectual property rights of others, the potential cost of such litigation (regardless of the strength of the Company's legal position) and the potential damages that the Company could be required to pay could be substantial.

In addition to patent protection, the Company relies on trade secrets, proprietary know-how and technological advances which it seeks to protect, in part, by confidentiality agreements with its collaborative partners, employees and consultants. There can be no assurance that these confidentiality agreements will not be breached, that the Company would have adequate remedies for any such breach, or that the Company's trade secrets, proprietary know-how and technological advances will not otherwise become known or be independently discovered by others.

Intense Competition The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Competitors of the Company 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 the Company or its collaborative partners. Acquisitions of competing companies and potential competitors by large pharmaceutical companies or others could enhance financial, marketing and other resources available to such competitors. As a result of academic and government institutions becoming increasingly aware of the commercial value of their research findings, such institutions are more likely to enter into exclusive licensing agreements with commercial enterprises, including competitors of the Company, to market commercial products. There can be no assurance that the Company's competitors will not succeed in developing technologies and drugs that are more effective or less costly than any which are being developed by the Company or which would render the Company's technology and future products obsolete and noncompetitive.

In addition, some of the Company's competitors have greater experience than the Company in conducting preclinical and clinical trials and obtaining FDA and other regulatory approvals. Accordingly, the Company's competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than the Company. 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, including certain patent and FDA marketing exclusivity rights that would delay the Company's ability to market certain products. There can be no assurance that drugs resulting from the Company's research and development efforts, or from the joint efforts of the Company and its collaborative partners, will be able to compete successfully with competitors' existing products or products under development or that they will obtain regulatory approval in the United States or elsewhere.

Uncertainty Associated with Preclinical and Clinical Testing Before obtaining regulatory approvals for the commercial sale of any of the Company's potential drugs, the drug candidates will be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. The Company is dependent on its collaborative partners to conduct clinical trials for drug candidates. Furthermore, there can be no assurance 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. 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 would have a material adverse effect on the Company's business, operating results and financial condition. See "Business-Government Regulation."

No Assurance of Market Acceptance There can be no assurance that any drugs successfully developed by the Company, independently or with its collaborative partners, if approved for marketing, will achieve market acceptance. The drugs which the Company is attempting to develop will 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 the Company will depend on a number of factors, including the establishment and demonstration of the clinical efficacy and safety of the Company's drug candidates, their potential advantage over existing therapies and reimbursement policies of government and third-party payers. There is no assurance that physicians, patients or the medical community in general will accept and utilize any drugs that may be developed by the Company independently or with its collaborative partners. Dependence on Key Personnel The Company is highly dependent upon the efforts of its senior management and scientific team, including its President and Chief Executive Officer. The Company does not maintain key man life insurance for any of its key employees and does not intend to obtain such insurance. The loss of the services of one or

#### 14

more of these individuals might impede the achievement of the Company's development objectives. Because of the specialized scientific nature of the Company's business, the Company is highly dependent upon its ability to attract and retain qualified scientific and technical personnel. 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 the Company's activities.

Concentration of Ownership Dr. David Ranney and Nicholas Madonia currently beneficially own approximately 13.3% and 7.9% respectively, of the issued and outstanding Common Stock. Dr. Ranney and Mr. Madonia have agreed not to sell any shares of Common Stock of the Company until January 11, 2001 without the approval of the placement agent of 1998 placement of securities. Richard Stone, currently beneficially owns 6.3% of the issued and outstanding Common Stock of Access. Mr. Stone has not signed a lock-up agreement, except as to the Shares he will receive in the Acquisition. See "Certain Relationships and Related Transactions."

Possible Volatility of Stock Price Stock prices for many technology companies fluctuate widely for reasons which may be unrelated to operating performance or new product or service announcements. Broad market fluctuations, earnings and other announcements of other companies, general economic conditions or other matters unrelated to Access and outside its control also could affect the market price of the Common Stock. See "Market For The Registrant's Common Equity And Related Stockholders Matters."

Limited Market for Common Stock Trading in Access' securities is presently conducted in the over-the-counter market on the OTC Bulletin Board. As a result, an investor may find it difficult to dispose of, or to obtain accurate quotations as to the price of the Company's securities. In addition, the Company's securities are subject to a rule that imposes additional sales practice requirements on broker-dealers who sell such securities to persons other than established customers and accredited investors (generally with assets of \$1,000,000, or annual income exceeding \$200,000, or \$300,000 together with their spouse). For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. Consequently, the rule may affect the ability of broker-dealers to sell their securities of the Company and may effect the ability of purchasers to sell their securities in the secondary market.

Effect of Certain Charter and By-Law Provisions; Possible Issuance of Preferred Stock Access' Certificate of Incorporation and By-laws contain provisions that may discourage acquisition bids for Access. This could limit the price that certain investors might be willing to pay in the future for shares of Common Stock. In addition, shares of Access 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 the Board of Directors may determine (including, for example, rights to convert into Common Stock). The rights of the holders of Common Stock will be subject to, and may be adversely affected by, the rights of the holders of any Access Preferred Stock that may be issued in the future. The issuance of Access 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, or discouraging a third party from acquiring, a majority of the outstanding voting Common Stock of Access.

Market Impact of Future Sales of Common Stock Sales of substantial amounts of shares of Access Common Stock in the public market could adversely affect the market price of the Common Stock. As of the date hereof, all outstanding shares of Common Stock are unrestricted and freely tradable or tradable under Rule 144 (as defined below); however, shareholders holding approximately 899,000 shares of Common Stock have agreed not to sell any such shares until January 11, 2001. There also are outstanding options, warrants and rights to purchase up to approximately 1.2 million shares of the Common Stock. The sale of a substantial number of shares of Common Stock could have a material adverse effect on the future market price of the Common Stock.

Absence of Dividends Access has not paid cash dividends on its Common Stock and does not anticipate paying cash dividends on Common Stock in the foreseeable future. See "Market For The Registrant's Common Equity And Related Stockholders Matters."

NASD Listing Requirements The Company's shares were delisted from the NASDAQ Small Cap Market effective April 27, 1995 for failure to meet certain financial criteria. The Common Stock continues to be traded in the over-the-counter market and reported on the OTC Bulletin Board. As such, the Common Stock, when recommended by a broker-dealer, is subject to the limitations of rule 15g-9 under the Exchange Act, which Rule imposes additional sales practices requirements on broker-dealers that sell the Common Stock (1) to persons other than (a) existing customers with a previous history of trading through such broker-dealer, (b) institutional accredited investors (for example, a bank or savings and loan association) and (c) a director and/or officer of the Company and/or the beneficial owner of 5% or

## 15

more of the Common Shares or (2) in transactions not exempt by the Rule. For transactions under Rules 15g-9, the broker-dealer must obtain written information from the prospective purchaser as to his or her financial situation, investment experience and investment objectives and, based on such information, reasonably determine that transactions in the security are suitable for that person and that the prospective investor (or his or her independent adviser) has sufficient knowledge and experience in financial matters so as to be reasonably expected to be capable of evaluating the risks of transactions in such security. The broker-dealer must also receive the purchaser's written agreement to the transaction prior to the sale. Certain broker-dealers, particularly if they are market makers in the Common Stock, will have to comply with the disclosure requirements of Rule 15g-2, 15g-3, 15g-4, 15g-5 and 15g-6 under the Exchange Act. Consequently, Rule 15g-9 and these other Rules may adversely affect the ability of brokerdealers to sell the Common Stock and also may adversely affect the ability of purchasers in this Offering to sell their shares in the secondary market.

The Company plans to file an NASD listing application as soon as it meets the listing requirements. However, the Company currently does not meet all of such listing requirements, including without limitation the minimum stock price criterion.

Penny Stock Regulation; Illiquid Securities The regulations of the Securities and Exchange Commission (the "Commission") promulgated under the Exchange Act require additional disclosure relating to the market for penny stock in connection with trades in any stock defined as a penny stock. Commission regulations generally define a penny stock to be an equity that has a market price of less than \$5.00 per share, subject to certain exceptions. Unless an exception is available, those regulations require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the risks associated therewith and impose various sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors (generally institutions). In addition, the broker-dealer must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and its salesperson in the transaction and monthly account statements showing the market value of each penny stock held in the customer's account. Moreover, brokerdealers who recommend such securities to persons other than established customers and accredited investors must make a special written suitability determination for the purchaser and receive the purchaser's written agreement to transactions prior to sale. Regulations on penny stocks could limit the ability of broker-dealers to sell the Company's securities and thus the ability of purchasers of the Company's securities to sell their securities in the secondary market.

Year 2000 Issue The Year 2000 ("Y2K") issue is the result of computer programs using two instead of four digits to represent the year. These

computer programs may erroneously interpret dates beyond the year 1999, which could cause system failures or other computer errors, leading to disruptions in operations.

The Company has developed a three-phase program to limit or eliminate Y2K exposures. Phase I is to identify those systems, applications and thirdparty relationships from which the Company has exposure to Y2K disruptions in operations. Phase II is the development and implementation of action plans to achieve Y2K compliance in all areas prior to the end of the third quarter of 1999. Also included in Phase II is the development of contingency plans which would be implemented should Y2K compliance not be achieved in order to minimize disruptions in operations. Phase III is the final testing or equivalent certification of testing of each major area of exposure to ensure compliance. The Company intends to complete all phases before the end of the third quarter of 1999.

The Company has identified three major areas determined to be critical for successful Y2K compliance: Area 1, which includes financial, research and development and administrative informational systems applications reliant on system software; Area 2, which includes research, development and quality applications reliant on computer programs embedded in microprocessors; and Area 3, which includes third-party relationships which may be affected by Area 1 and 2 exposures which exist in other companies.

With respect to Area 1, the Company has completed an internal review and contacted all software suppliers to determine major areas of Y2K exposure. In research, development and quality applications (Area 2), the Company has worked with equipment manufactures to identify our exposures. With respect to Area 3, the Company has evaluated our reliance on third parties in order to determine whether their Y2K compliance will adequately assure our uninterrupted operations.

The Company has completed Phase I of our Y2K program with respect to all three of the major areas. The Company relies on PC-based systems and does not expect to incur material costs to transition to Y2K compliant systems in its internal operations. However, even if the internal systems of the Company are not materially affected by the Y2K Issue, the Company could be affected by third-party relationships which, if not Y2K compliant prior to the end of 1999, could

#### 16

have a material adverse impact on our operations. Because the Company has not completed Phase II contingency planning, the Company can not describe what action the Company would take in any of the areas should Y2K compliance not be achievable in time. As such, there can be no assurance that the Y2K Issue will not have a material adverse effect on the Company's business, financial condition or results of operations.

As of December 31, 1998, we have identified costs related to replacement or remediation and testing of our Area 1 computer information systems. Having completed the Phase I evaluation, total costs to date are \$5,000. We estimate the potential future cost of our Y2K compliance programs is \$25,000. The funds for these costs will be part of our current working capital. These costs will be expensed as incurred except for equipment related costs.

## **ITEM 2. PROPERTIES**

Access maintains one facility of approximately 9,100 square feet for administrative offices and laboratories in Dallas, Texas. Access has a lease agreement for the facility, which terminates in November 2002. However, the Company has an option for early termination. Adjacent space is available for expansion which the Company believes would accommodate growth for the foreseeable future.

## ITEM 3. LEGAL PROCEEDINGS

Access is not a party to any material legal proceedings.

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

#### PART II

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

Price Range of Common Stock and Dividend Policy

The Company's Common Stock trades on the OTC Bulletin Board under the trading symbol AXCS. The following table sets forth, for the periods indicated, the high and low closing prices for the Common Stock as reported by the OTC Bulletin Board for the Company's past two fiscal years. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

Common Stock

<TABLE> <CAPTION>

	High	Low	
< <u>S</u> >	<c></c>	<c></c>	>
Fiscal Year Ended Decemb	er 31, 19	98	
First quarter	\$14	4-1/16 \$	\$ 5
Second quarter		5-5/8	3-1/16
Third quarter	-	3-25/64	1-11/64
Fourth quarter		3-37/64	1-5/8
Fiscal Year Ended Decemb	ver 31-19	97	

riscar rear Endeu December 5	1,1///	
First quarter	\$25-5/8	\$14-3/8
Second quarter	17-3/1	6 7-1/2
Third quarter	10	3-3/4
Fourth quarter	14-1/1	6 4-1/16

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#### 17

The Company has never declared or paid any cash dividends on its Preferred Stock or Common Stock and does not anticipate paying any cash dividends in the foreseeable future. The payment of dividends, if any, in the future is within the discretion of the Board of Directors and will depend on Access' earnings, its capital requirements and financial condition and other relevant facts. The Company currently intends to retain all future earnings, if any, to finance the development and growth of the Company's business.

The number of record holders of Access Common Stock at March 25, 1999 was approximately 5,000. On March 25, 1999, the closing sale price for the Common Stock as quoted on the OTC Bulletin Board was \$2.92. There were 3,429,402 shares of Common Stock outstanding at March 25, 1999.

To date, no preferred shares have been issued.

Recent Sales of Unregistered Securities

None

## ITEM 6. SELECTED FINANCIAL DATA (Thousands, Except for Net Loss Per Share)(1,2)

The following data, insofar as it relates to each of the years in the five year period ended December 31, 1998, has been derived from the audited financial statements of Access and notes thereto appearing elsewhere herein. 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 10K.

<TABLE> <CAPTION>

1998	1997	1996	1995	1994
<c></c>	<c></c>	<c></c>	<c></c>	<c></c>

<S>

Consolidated Statement of Operations Data: Total Revenues \$ - \$ 435 \$ 167 \$ 690 \$ 1,039 Operating Loss (3,433) (4,524) (11,613) (1,046) (466) Other Income 91 58 11 96 59 Interest Expense 58 19 22 36 45 (3,397) (4,441) (11,462) (1,099) Loss Before Income Taxes (476) Income taxes Net Loss (3,397) (4,441) (11,462) (1,099) (476) Common Stock Data: Net Loss Per Basic and

Diluted Common Share \$(1.28) \$(2.80) \$(7.68) \$(1.86) \$(.85) Weighted Average Basic and Diluted Common Shares

Outstanding 2,654 1,584 1,492 592 558

December 31,

-	1998	199	97 1	996	1995	 1994 	
Consolidated Balan	ce She	et Dat	a:				
Total Assets	\$ 2	2,351	\$ 1,44	¥7 \$4,	928 \$	424 \$ 1	,261
Unearned Revenue		-		11	0 11	0 -	
Total Liabilities		556	848	868	3 77	3 731	
Stockholders' Equit	y (Def	icit) 1	,795	599	4,060	(349)	531

  |  |  |  |  |  |  |

- (1) Reflects Company data for 1998, 1997 and 1996 and API data for the years 1995 and 1994. Net Loss Per Basic and Diluted Common Share and Weighted Average Basic and Diluted Common Shares Outstanding are adjusted by the conversion factor 3.824251 used for the merger of API with the Company.
- (2) All share and per share amounts have been adjusted to reflect the one for twenty reverse stock split in June 1998.

On January 25, 1996, the Company shareholders, at a Special Meeting, approved the merger with Access Pharmaceuticals, Inc. ("API"), a Texas corporation. Under the terms of the agreement, API was merged into the Company with Chemex as the surviving entity. Chemex also changed its name to Access Pharmaceuticals, Inc. and the operations of the consolidated company are now based in Dallas, Texas. Shareholders of both companies approved the merger.

#### 18

As a result of the merger, and at time of the merger, the former API stockholders owned approximately 60% of the issued and outstanding shares of the Company. Generally accepted accounting principles require that a company whose stockholders retain the controlling interest in a combined business be treated as the acquiror for accounting purposes. As a consequence, the merger is being accounted for as a "reverse acquisition" for financial reporting purposes and API has been deemed to have acquired an approximate 60% interest in Chemex. Despite the financial reporting requirement to account for the acquisition as a "reverse acquisition", the Company remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes.

Subsequent to the Merger of API into Access, the Company is now managed by the former management of API and the focus of the Company has changed to the development of enhanced delivery of parenteral therapeutic and diagnostic imaging agents and topical delivery systems through the utilization of its patented and proprietary technology.

On December 9, 1997, a wholly-owned subsidiary of the Company acquired and merged with Tacora Corporation ("Tacora"), a privately-held pharmaceutical company based in Seattle, Washington; Tacora became a wholly-owned subsidiary of the Company. The Company used the purchase method of accounting for the purchase of Tacora. 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, plus up to 137,500 shares in additional Common Stock if certain milestones are met. The share price to be used will range between \$2.50 and \$6.50 per share (range of value of shares is \$344,000 to \$894,000), depending on when the milestones are met. All milestone conditions expire in June 2000. The aggregate purchase price has been allocated to the net assets acquired based on management's estimates of the fair values of assets acquired and liabilities assumed. The excess purchase price over the fair value of Tacora's net identifiable assets of \$579,544 was recorded and written off in the fourth quarter of 1997 due to an impairment of the excess purchase price based on estimated future cash flows.

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

#### Overview

Access Pharmaceuticals, Inc. (together with its subsidiary, "Access" or the "Company") is a Delaware corporation in the development stage. The Company is a site-directed drug targeting company using bioresponsive carriers to target and control the release of therapeutic agents into sites of disease activity and significantly improve the side effect profile of the agents. The Company has proprietary patents or rights to four technology platforms: synthetic polymers, Residerm TM, carbohydrate targeting technology and selective muscle and nerve delivery systems. In addition, Access' partner Block is marketing Aphthasol TM in the United States, the first FDA approved product for the treatment of canker sores. Access is currently licensing this product in certain international markets and developing new delivery forms.

In connection with the merger ("Merger") of Access Pharmaceuticals, Inc., a Texas corporation ("API"), with and into Chemex Pharmaceuticals, Inc. ("Chemex") on January 25, 1996, the name of Chemex was changed to Access Pharmaceuticals, Inc. ("Access" or the "Company").

As a result of the Merger and immediately after the Merger, the former API Stockholders owned approximately 60% of the issued and outstanding shares of the Company. Generally accepted accounting principles require that a company whose stockholders retain the controlling interest in a combined business be treated as the acquiror for accounting purposes. As a consequence, the merger was accounted for as a "reverse acquisition" for financial reporting purposes and API was deemed to have acquired an approximate 60% interest in Chemex. Despite the financial reporting requirement to account for the acquisition as a "reverse acquisition," Chemex remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes.

Subsequent to the Merger of API into Access, the Company has been managed by the former management of API and the focus of the Company has changed to a drug delivery company using advanced drug carrier technology for application in cancer treatment, dermatology and imaging. In addition, the Company has developed a drug to treat canker sores that was sold to Block and is currently being marketed in the United States by Block subject to a royalty agreement with the Company.

#### 19

On June 18, 1998, in conjunction with the first closing of a private placement, the Company effected a recapitalization of the Company through a one-for-twenty reverse stock split of its common stock, \$0.04 par value per share, which decreased the number of authorized shares of common stock from 60.0 million, at \$0.04 par value per share, to 20.0 million shares, \$0.01 par value per share (the "Common Stock"), and decreased the authorized shares of preferred stock of the Company from 10.0 million to 2.0 million (the "Recapitalization"). The Recapitalization decreased the number of outstanding shares of Common Stock from approximately 41.5 million to 2.1 million.

All share numbers and prices referenced herein have been adjusted to reflect the Recapitalization.

An investment bank has been engaged to assist the Company in raising funds to support the Company's research and development activities. As discussed below, from March to July 1998, the Company raised an aggregate of \$5.0 million. The Company is currently seeking to raise up to an additional \$8.0 million to support product development activities. There can be no assurance, however, that any such equity offerings will occur, or that additional financing will be available from any of these sources or, if available, will be available on acceptable or affordable terms.

In 1998, the Company, assisted by an investment bank, raised \$1,200,000 in gross proceeds (\$725,000 received on March 20, 1998 and \$475,000 received on April 11, 1998) less cash issuance costs of \$47,000, from the placement of 48 units, each unit consisting of 8,333 shares of Common Stock and warrants to purchase 8,333 shares of Common Stock at an exercise price of \$3.00 per share. The placement agent received warrants to purchase 44,527 shares of Common Stock at \$3.00 per share, in accordance with the offering terms and elected to receive 45,277 shares of Common Stock in lieu of certain sales commissions and expenses.

On June 18, 1998, the Company, assisted by the same investment bank, raised an aggregate of \$2.9 million in gross proceeds, less cash issuance costs of \$202,000, from the first closing of a private placement of 953,573 shares of Common Stock at \$3.00 per share. The placement agent for such offering received warrants to purchase 101,653 shares of Common Stock at \$3.00 per share, in accordance with the offering terms and elected to receive 62,949 shares of Common Stock in lieu of certain sales commissions and expenses.

On July 30, 1998, the Company, assisted by the same investment bank, raised an aggregate of \$900,000 in gross proceeds, less cash issuance costs of \$24,000, from the second closing of a private placement of 300,000 shares of Common Stock at \$3.00 per share. The placement agent for such offering received warrants to purchase 33,445 shares of Common Stock at \$3.00 per share, in accordance with the offering terms and elected to receive 34,450 shares of Common Stock in lieu of certain sales commissions and expenses.

Issuance costs for the above placements totaled \$405,000. The proceeds of the offering will be used to fund research and development, working capital, acquisitions of complementary companies or technologies and general corporate purposes.

If and when the Company satisfies all listing requirements, the Company intends to submit an application for listing on NASDAQ or an alternate exchange. There can be no assurances that the Company will be listed on NASDAQ or an alternate exchange.

On December 9, 1997, a wholly-owned subsidiary of Access acquired and merged with Tacora Corporation ("Tacora"), a privately-held pharmaceutical company based in Seattle, Washington; Tacora became a wholly-owned subsidiary of Access. The Company used the purchase method of accounting for the purchase of Tacora. 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 plus up to 137,500 shares if additional Common Stock if certain milestones are met. The share price to be used will range between \$2.50 and \$6.50 per share (range of value of shares is \$344,000 to \$894,000), depending on when the milestones are met. All milestone conditions expire in June 2000. The aggregate purchase price has been allocated to the net assets acquired based on management's estimation of the fair value of assts acquired and liabilities assumed. The excess purchase price over the fair value of Tacora's net identifiable assets of \$580,000 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. Operations of Tacora have been included in the Company's consolidated financial statements since the date of acquisition. Pro forma disclosure relating to the Tacora acquisition is not presented as the impact is immaterial to the Company.

Since its inception, Access has devoted its resources primarily to fund its research and development programs. The Company has been unprofitable since inception and to date has not received any revenues from the sale of products. No

assurance can be given that the Company will be able to generate sufficient product revenues to attain profitability on a sustained

basis, if at all. The Company expects to incur losses for the next several years as it continues to invest in product research and development, preclinical studies, clinical trials and regulatory compliance. At December 31, 1998, the Company's accumulated deficit was approximately \$23.1 million.

## Recent Developments

On June 8, 1998, the Company entered into an agreement to license from Block Drug Company the rights to amlexanox oral paste 5% for certain international markets. Amlexanox oral paste 5% was jointly developed by the Company and Block Drug Company, and was subsequently purchased by Block Drug Company with the Company receiving an up front fee and future royalty payments. Amlexanox oral paste 5% is currently marketed in the United States by Block Drug under the trademark Aphthasol TM. Aphthasol TM was launched to the dental market in December 1997 and was launched to the general practice physician market in June 1998.

Access has announced agreements or letters of intent with the following international partners to market amlexanox 5% paste: In the UK and Ireland Access signed an agreement on August 18, 1998 with Strakan Limited. Under the terms of the agreement, Strakan will bear all costs associated with the regulatory process in the UK and the European community, and will pay milestones based on cumulative sales and a royalty on sales. On August 20, 1998 Access signed a Letter of Intent with Paladin Labs, Inc. for marketing rights for amlexanox in Canada. Paladin will bear all costs associated with gaining regulatory approval in Canada, and will pay milestones based on cumulative sales revenue and a royalty on sales. Paladin is a subsidiary of PharmaScience. Access signed a license agreement in January 1999 with Meda AB of Sweden for licensing rights in Sweden, Finland, Norway, Denmark, Latvia, Estonia, Lithuania and Iceland. Under the terms of the agreement, Meda will make an up-front license payment, pay milestone payments and a royalty on sales. Access signed a Letter of Intent on October 15, 1998 with Laboratoios Dr. Esteve, to license amlexanox for Italy, Spain, Portugal and Greece. Esteve will make an up-front license payment, pay milestone payments and will pay a royalty on sales.

Access signed an agreement on August 25, 1998 with Atrix Laboratories, Inc. ("Atrix") to incorporate amlexanox in the proprietary mucoadhesive technologies being developed by Atrix. Atrix is developing an innovative bioerodiable mucoadhesive ("BEMA") delivery system, which is a thin film that adheres to the oral mucosa and erodes over time delivering the drug into the tissue. Also under development is a film forming mucocutaneous adsorption ("MCA") gel that deposits a film upon application to mucosal surfaces adhering well to wet or damp skin, this technology can also be adapted to an aerosal spray delivery system.

It is anticipated that within three months a formulation could be ready for clinical testing. Access will fund the Atrix project development activities; however, Block Drug Company will share in the development costs by way of a reduction in the royalty Access will pay Block for international sales. The international rights to any product resulting from the collaboration with Atrix will be out-licensed by Access to its amlexanox licensing partners. Atrix will receive a royalty on all worldwide sales of products incorporating its propriety technology.

On March 1, 1999 the Company and a wholly owned subsidiary of the Company entered into a merger agreement with Virologix Corporation ("Virologix"), whereby Virologix will become a wholly owned subsidiary of the Company. The closing of the merger is subject to certain conditions, including the condition that the Company raise at least \$3.0 million in equity financing.

Virologix is a privately held company focused on the development of product candidates for the prevention and treatment of viral diseases including HIV. Under the terms of the agreement the Virologix shareholders will receive 1,000,000 shares of common stock of the Company. It is anticipated that the closing of the acquisition will take place during the second quarter of 1999.

Liquidity and Capital Resources

As of March 24, 1999 the Company's principal source of liquidity is \$1,009,000 of cash and cash equivalents. Working capital as of December 31, 1998 was \$1,009,000, representing an increase in working capital of \$1,225,000 as compared to the working capital deficit as of December 31, 1997 of \$216,000. The increase in working capital at December 31, 1998 was due to \$4.6 million in net proceeds received from the private placement of the Company's Common Stock sold in June and July 1998 and the private placement of units in March and April 1998, net of monthly operating expenses.

#### 21

Since its inception, the Company's expenses have significantly exceeded its revenues, resulting in an accumulated deficit of \$23.1 million at December 31, 1998. The Company has funded its operations primarily through private sales of its equity securities, contract research payments from corporate alliances and the January 1996 merger.

The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend in the future, substantial funds to complete its planned product development efforts. The Company expects that its existing capital resources will be adequate to fund the Company's operations through the second quarter of 1999. The Company is dependent on raising additional capital to fund the development of its technology and to implement its business plan. Such dependence will continue at least until the Company begins marketing its new technologies.

If anticipated revenues are delayed or do not occur or the Company is unsuccessful in raising additional capital on acceptable terms, the Company would be required to curtail research and development and general and administrative expenditures so that working capital would cover reduced operations into the third quarter of 1999. There can be no assurance, however that changes in the Company's operating expenses will not result in the expenditure of such resources before such time.

The Company will require substantial funds to conduct research and development programs, preclinical studies and clinical trials of its potential products. The Company's 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 for research, development and commercialization of products with corporate partners; continued scientific progress in the Company's 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; and the ability to establish and maintain effective commercialization activities and arrangements.

The Company intends to seek additional funding through research and development or licensing arrangements with potential corporate partners, public or private financing, or from other sources. The Company does not have any committed sources of additional financing and there can be no assurance that additional financing will be available on favorable terms, if at all. In the event that adequate funding is not available, the Company may be required to delay, reduce or eliminate one or more of its research or development programs or obtain funds through arrangements with corporate collaborators or others that may require the Company to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than the Company would otherwise seek. Insufficient financing may also require the Company to relinquish rights to certain of its technologies that the Company would otherwise develop or commercialize itself. If adequate funds are not available, the Company's business, financial condition and results of operations will be materially and adversely affected.

## **Results of Operations**

Comparison of Years Ended December 31, 1998 and 1997

Net revenues for 1997 were \$435,000 as compared to no revenues in 1998. 1997 revenues were comprised of licensing income from an ongoing agreement with an emerging pharmaceutical company which made certain milestone payments and will make royalty payments in the future if a product is developed from the technology. In addition, \$110,000 of option income was recorded in 1997 from an agreement with a pharmaceutical company. The agreement is no longer in effect.

Total research and development spending for 1998 was \$1,756,000 as compared to \$2,433,000 for the same period in 1997, a decrease of \$677,000. The decrease in expenses was due to: lower external contract research costs- \$427,000; lower salary and related costs- \$149,000; lower equipment rent- \$94,000; lower travel expenses- \$47,000; and other net decreases totaling- \$116,000 offset by cost to manufacture the polymer platinate product for testing- \$145,000. If the Company is successful in raising additional capital, research spending is expected to increase in future quarters as the Company intends to hire additional scientific management and staff and will accelerate activities to develop the Company's product candidates. If the Company is not successful in raising additional capital, research spending will be curtailed.

General and administrative expenses were \$1,464,000 for 1998, a decrease of \$320,000 as compared to the same period in 1997. The decrease was primarily due to the following: lower general business consulting fees and expenses- \$331,000; and lower director and officer insurance costs due to a lower insurance premium- \$56,000; other net decreases

22

totaling- \$18,000; offset by higher patent expenses- \$29,000; and higher shareholder expenses relating to an additional shareholder meeting and the reverse stock split- \$56,000.

Depreciation and amortization was \$213,000 for 1998 as compared to \$162,000 for the same period in 1997 reflecting additional depreciation for assets acquired in the Tacora merger and a full year of amortization of licenses.

Interest and miscellaneous income was \$58,000 for 1998 as compared to \$119,000 for the same period in 1997, a decrease of \$61,000. The decrease was due to lower cash balances in 1998.

Interest expense was \$22,000 for 1998 as compared to \$36,000 for the same period in 1997, a decrease of \$14,000. The decrease was due to the pay down and payoff of equipment leases.

Accordingly, this resulted in a loss for the twelve months ended December 31, 1998 of \$3,397,000, or a \$1.28 basic and diluted loss per common share.

Comparison of Years Ended December 31, 1997 and 1996

Revenues for 1997 were \$435,000 as compared to \$167,000 in 1996, an increase of \$268,000. Revenues for 1997 were comprised of \$325,000 of licensing income from an ongoing agreement with an emerging pharmaceutical company. The agreement provides for royalty payments if a product is developed from the technology. In addition \$110,000 of option income was recorded in 1997. Revenues for 1996 were comprised of option income with a pharmaceutical company.

Total research and development spending for 1997 was \$2,433,000 as compared to \$1,405,000 for the same period in 1996, an increase of \$1,028,000. The increase in research and development expenses was due to the following: external research expenditures- \$683,000 primarily due to additional funding of Polymer Platinate at University of London and research at Duke University; salaries and related expenses- \$158,000 due to hiring of additional scientists; equipment rental and maintenance costs-\$82,000; travel and entertainment- \$44,000 due to project management of external research; scientific consulting- \$43,000 due to additional consulting and manpower for the ongoing projects; and other net increases totaling \$83,000. The increase in research and development expenses is offset by lower moving expenses- \$65,000 due to the relocation of scientists in 1996.

Total general and administrative expenses were \$1,784,000 in 1997, a decrease of \$154,000 as compared to the same period in 1996. The decrease in spending was due to the following decreases in: business consulting fees- \$109,000 primarily due to the fair value of warrants issued

in 1997 for consulting being less than the fair value of the warrants issued in 1996; patent expenses- \$74,000 due to fewer initial patent filings in 1997 as compared to 1996; lower moving expenses- \$44,000 due to the moving expenses associated with the hiring of a business development vice president in 1996; and other decreases of \$27,000. The decreases are offset by higher salaries and related expenses- \$111,000 due to a full twelve months of salaries in 1997 for all administrative employees as compared to a partial period in 1996.

Interest expense of \$36,000 was \$9,000 lower in 1997 versus 1996 due to the decrease of the outstanding balance of capital lease obligations. Interest expense will increase in 1998 due to the addition of capital leases from the Tacora acquisition.

Depreciation and amortization increased to \$162,000 in 1997 from \$123,000 in 1996, an increase of \$39,000. The increase is due to the amortization of \$25,000 of licenses and one month of depreciation and amortization of the Tacora assets.

Excess purchase price over the fair value of Tacora's net assets of \$580,000 was recorded and written off in the fourth quarter of 1997. In 1996, excess purchase price over the fair value of Chemex's net assets of \$8,314,000 was recorded and written off due to an immediate impairment of the excess purchase price.

Total expenses were \$4,849,000, including \$580,000 of excess purchase price written off for the Tacora purchase, which resulted in a loss for the twelve months of \$4,441,000, or \$2.80 per share.

23 New Accounting Standards

In June 1998, the FASB issued Statement of Financial Accounting Standards No. 133 "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133"), which is effective for financial statements for fiscal years beginning after June 15, 1999, and which will apply to the Company beginning June 1, 2000. SFAS 133 establishes accounting and reporting standards for derivative instruments and for hedging activities. The Company does not believe that the new standard will have any significant effect on its future results of operations.

In April 1998, the Accounting Standards Executive Committee of the American Institute of Certified Public Accountants issued a Statement of Position ("SOP") effective for financial statements for fiscal years beginning after December 15, 1998, which will apply to the Company beginning with its fiscal year ended December 31, 1999. SOP 98-5, "Reporting on the Costs of Start-Up Activities," Requires such costs to be expensed as incurred instead of capitalized and amortized. The Company does not expect the adoption of this SOP to have any material effect on its future results of operations.

Year 2000 Issue

The Year 2000 ("Y2K") issue is the result of computer programs using two instead of four digits to represent the year. These computer programs may erroneously interpret dates beyond the year 1999, which could cause system failures or other computer errors, leading to disruptions in operations.

The Company has developed a three-phase program to limit or eliminate Y2K exposures. Phase I is to identify those systems, applications and thirdparty relationships from which the Company has exposure to Y2K disruptions in operations. Phase II is the development and implementation of action plans to achieve Y2K compliance in all areas prior to the end of the third quarter of 1999. Also included in Phase II is the development of contingency plans which would be implemented should Y2K compliance not be achieved in order to minimize disruptions in operations. Phase III is the final testing or equivalent certification of testing of each major area of exposure to ensure compliance. The Company intends to complete all phases before the end of the third quarter of 1999.

The Company has identified three major areas determined to be critical for successful Y2K compliance: Area 1, which includes financial, research and development and administrative informational systems applications reliant

on system software; Area 2, which includes research, development and quality applications reliant on computer programs embedded in microprocessors; and Area 3, which includes third-party relationships which may be affected by Area 1 and 2 exposures which exist in other companies.

With respect to Area 1, the Company has completed an internal review and contacted all software suppliers to determine major areas of Y2K exposure. In research, development and quality applications (Area 2), the Company has worked with equipment manufactures to identify our exposures. With respect to Area 3, the Company has evaluated our reliance on third parties in order to determine whether their Y2K compliance will adequately assure our uninterrupted operations.

The Company has completed Phase I of our Y2K program with respect to all three of the major areas. The Company relies on PC-based systems and does not expect to incur material costs to transition to Y2K compliant systems in its internal operations. However, even if the internal systems of the Company are not materially affected by the Y2K Issue, the Company could be affected by third-party relationships which, if not Y2K compliant prior to the end of 1999, could have a material adverse impact on our operations. Because the Company has not completed Phase II contingency planning, the Company can not describe what action the Company would take in any of the areas should Y2K compliance not be achievable in time. As such, there can be no assurance that the Y2K Issue will not have a material adverse effect on the Company's business, financial condition or results of operations.

As of December 31, 1998, we have identified costs related to replacement or remediation and testing of our Area 1 computer information systems. Having completed the Phase I evaluation, total costs to date are \$5,000. We estimate the potential future cost of our Y2K compliance programs is \$25,000. The funds for these costs will be part of our current working capital. These costs will be expensed as incurred except for equipment related costs.

ITEM 7(a). MARKET RISK

The Company is not exposed to any market risks, as defined.

24 ITEM 8. FINANCIAL AND SUPPLEMENTARY DATA

The response to this Item is submitted as a separate section of this report.

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

KPMG LLP was previously the principal accountants for Access Pharmaceuticals, Inc. On October 22, 1998, that firm resigned. The decision to change accountants was not recommended by the audit committee of the board of directors.

In connection with the audits of fiscal years ended December 31, 1997 and 1996, and the subsequent interim period through October 22, 1998, there were no disagreements with KPMG LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements if not resolved to their satisfaction would have caused them to make reference in connection with their opinion to the subject matter of the disagreement.

KPMG LLP's independent auditors' report on the consolidated financial statements of Access Pharmaceuticals, Inc. and subsidiary as of and for the years ended December 31, 1997 and 1996, contained a separate paragraph stating that "the Company has suffered recurring losses from operations and has a net capital deficiency, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 11. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty."

Effective December 15, 1998, the Company engaged Grant Thornton LLP, independent certified public accountants, as its principal accountants. During the last two fiscal years, the Company did not consult with Grant

Thornton LLP regarding any of the matters or events set forth in Item 304 (a) (2) (i) and (ii) of Regulation S-K.

### 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 1999 Annual Meeting of Stockholders to be held on June 28, 1999 and is incorporated by reference. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days subsequent to December 31, 1998.

## ITEM 11. EXECUTIVE COMPENSATION

The information requested by this item will be contained in the Company's definitive Proxy Statement and is incorporated by reference. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days subsequent to December 31, 1998.

## 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 by reference. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days subsequent to December 31, 1998.

## 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 by reference. Such Proxy Statement will be filed with the Securities and Exchange Commission not later than 120 days subsequent to December 31, 1998.

#### 25 PART IV

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

a. Financial Statements and Exhibits

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

## Page

Independent Auditors' Report of Grant Thornton LLP	F-1
Independent Auditors' Report of KPMG LLP	F-2
Independent Auditors' Report of Smith Anglin and Company	F-3
Consolidated Balance Sheets at December 31, 1998 and 1997	F-4
Consolidated Statements of Operations for the three years	
ended December 31, 1998 and the period from	
February 24, 1988 (Inception) to December 31, 1998	F-5
Consolidated Statements of Stockholders' Equity (Deficit)	
for the period from February 24, 1988 (Inception) to	
December 31, 1998 F-6	
Consolidated Statements of Cash Flows for the three years	
ended December 31, 1998 and the period from	
February 24, 1988 (Inception) to December 31, 1998	F-8
Notes to Consolidated Financial Statements F-	9

2. Financial Statement Schedule

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

3. Exhibits

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 Company's Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)

3.0 Articles of incorporation and bylaws:

3.1 Certificate of Incorporation (Incorporated by Reference to Exhibit 3(a) of the Company's 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 the Company's 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 the Company's 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 the Company's 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 the Company's 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 the Company's Form 10-Q for the quarter ended June 30, 1998)

26 3.0 Exhibits (continued) Exhibit Number

10.0Material contracts:

10.1 Irrevocable Assignment of Proprietary Information with Dr. Charles G. Smith (Incorporated by reference to Exhibit 10.6 of the Company's Form 10-K for the year ended December 31, 1991)

10.2 Asset Purchase and Royalty Agreement between Block Drug Company, Inc. and the Company dated June 7, 1995 (Incorporated by reference to Exhibit 10.28 of the Company's Form 10-Q for the quarter ended June 30, 1995)

\*10.3 1995 Stock Option Plan (Incorporated by reference to Exhibit F of the Company's Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)

10.4 Stockholder's Agreement dated October 1995 between Access Pharmaceuticals, Inc. and Dr. David F. Ranney (Incorporated by reference to Exhibit A of the Company's 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 Company's 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 Access Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.17 of the Company's Form 10-K for the year ended December 31, 1995)

10.7 Lease Agreement between Pollock Realty Corporation and the Company dated July 25, 1996 (Incorporated by reference to Exhibit 10.19 of the Company's 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

10.9 License Agreement between The Dow Chemical Company and the Company dated June 30, 1997. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.12 of the Company's Form 10-Q for the quarter ended September 30, 1997)

10.10 Agreement of Merger and Plan of Reorganization, dated May 23, 1997 among the Company, Access Holdings, Inc and Tacora Corporation

10.11 License Agreement between Strakan Limited and the Company dated February 26, 1998 (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.12 of the Company's Form 10Q for the quarter ended March 31, 1998)

10.12 Agreement between Access Pharmaceuticals, Inc. and Block Drug Company, Inc. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.13 of the Company's Form 10Q for the quarter ended June 30, 1998)

10.13 Sales Agency Agreement. (Incorporated by reference to Exhibit 10.14 of the Company's Form 10Q for the quarter ended June 30, 1998)

10.14 Registration Rights Agreement. (Incorporated by reference to Exhibit 10.15 of the Company's Form 10Q for the quarter ended June 30, 1998)

\*10.15 Employment Agreement of Mr. Kerry P. Gray (Incorporated by reference to the Company's Registration Statement on Form SB-2 dated January 11, 1999, Commission File No. 333-62463)

10.16 Letter Agreement between the Company and David F. Ranney (Incorporated by reference to the Company's Registration Statement on Form SB-2 dated January 11, 1999, Commission File No. 333-62463)

10.17 License Agreement between Block Drug Company and the Company dated December 21, 1998 (Confidential Treatment Requested)

27

3.0 Exhibits (continued) Exhibit Number

21. Subsidiaries of the registrant

23.0 Consent of Experts and Counsel

23.1 Consent of Grant Thornton LLP

23.2 Consent of KPMG LLP

23.3 Consent of Smith, Anglin & Co.

27.1 Financial Data Schedule

\* 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.

On December 18, 1998, the Registrant filed a Current Report on Form 8-K related to Changes in the Registrant's Certifying Accountants. Effective December 15, 1998, the Company engaged Grant Thornton LLP as its principal accountants. During the last two fiscal years, the Company did not consult Grant Thornton LLP regarding any of the matters or events set forth in Item 304 (a) (2) (i) and (ii) of Regulation S-K.

## 28 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.

By: /s/ Kerry P. Gray

Date March 29, 1999

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, 1999	By:/s/ Kerry P. Gray
	Kerry P. Gray President and Chief Executive Officer, Director
Date March 29, 1999	By:/s/ J. Michael Flinn
	J. Michael Flinn, Director
Date March 29, 1999	By:/s/ Stephen B. Howell
	Stephen B. Howell, Director
Date March 29, 1999	By:/s/ Max Link
	Max Link, Director
Date March 29, 1999	By:/s/ Herbert H. McDade, Jr.
	Herbert H. McDade, Jr., Director
	29

Report of Independent Certified Public Accountants

Board of Directors and Stockholders Access Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Access Pharmaceuticals, Inc. and subsidiary (a development stage company) as of December 31, 1998, the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the year then ended, and the consolidated statements of operations and cash flows for the period February 24, 1988 (inception) to December 31, 1998. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. The cumulative statements of operations, and cash flows for the period February 24, 1988 (inception) to December 31, 1998 include amounts for the period from February 24, 1988 to December 31, 1988 and for each of the nine years in the period ended December 31, 1997, which were audited by other auditors whose reports have been furnished to us and are included herein. Our opinion, insofar as it relates to the amounts included for the period February 24, 1988 through December 31, 1997, is based solely on the reports of the other auditors.

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

In our opinion, based on our audit and the reports of the other auditors included herein, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Access Pharmaceuticals, Inc. and subsidiary as of December 31, 1998, and the consolidated results of their operations and their consolidated cash flows for the year then ended and for the period February 24, 1988 to December 31, 1998, in conformity with generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 11 to the consolidated financial statements, the Company has suffered recurring losses from operations and has incurred negative cash flows from operations since inception. These matters raise substantial doubt about its ability to continue as a going concern. Management's plan's in regard to these matters are also described in Note 11. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

GRANT THORNTON LLP

Dallas, Texas February 12, 1999

> F-1 Report of Independent Certified Public Accountants

Board of Directors and Stockholders Access Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Access Pharmaceuticals, Inc. and subsidiary (a development stage company) as of December 31, 1997 and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 1997 and for the period February 24, 1988 (inception) to December 31, 1997. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. The cumulative statements of operations, stockholders' equity (deficit), and cash flows for the period February 24, 1988 (inception) to December 31, 1997 include amounts for the period from February 24, 1988 (inception) to December 31, 1988 and for each of the years in the six-year period ending December 31, 1994, which were audited by other auditors whose report has been furnished to us and is included herein, and our opinion, insofar as it relates to the amounts included for the period February 24, 1988 (inception) through December 31, 1994, is based solely on the report of the other auditors.

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

In our opinion, based on our audits and report of the other auditors included herein, the consolidated financial statements for the two-year period ended December 31, 1997 referred to above present fairly, in all material respects the financial position of Access Pharmaceuticals, Inc. and subsidiary (a development stage company) as of December 31, 1997 and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 1997 and for the period February 24, 1988 (inception) to December 31, 1997, in conformity with generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 11 to the consolidated financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plan's in regard to these matters are also described in note 11. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ KPMG LLP

KPMG LLP

Dallas, Texas March 24, 1998

> F-2 Report of Independent Certified Public Accountants

Board of Directors and Stockholders Access Pharmaceuticals, Inc.

We have audited the accompanying statements of operations, stockholders' equity and cash flows of Access Pharmaceuticals, Inc. (a development stage company) for the period February 24, 1988 (inception) through December 31, 1994. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the period February 24, 1988 (inception) through December 31, 1994, in conformity with generally accepted accounting principles.

/s/ Smith, Anglin & Co.

Smith, Anglin & Co.

Dallas, Texas September 21, 1995

## F-3

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

## CONSOLIDATED BALANCE SHEETS

## <TABLE> <CAPTION>

## December 31,

ASSETS	1998	1997
<s> Current assets Cash and cash equivalents Accounts receivable Prepaid expenses and other</s>	-	7,000 \$ 438,000 1,000
Total current assets	1,541,00	0 490,000
Property and equipment, n	et (Note 5)	227,000 422,000
Licenses, net (Note 1)	425,00	00 475,000
Investments	150,000	50,000
Other assets	8,000	10,000
Total assets	\$2,351,000	\$1,447,000

## LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities Accounts payable and accrued ex Royalties payable (Note 3) Accrued insurance premiums Current portion of obligations un capital leases (Note 6)	tpenses \$ 395,000 \$ 434,000 - 53,000 38,000 38,000 der 99,000 181,000		
Total current liabilities	532,000 706,000		
Obligations under capital leases, net of current portion (Note 6)	24,000 142,000		
Total liabilities	556,000 848,000		
Commitments and contingencies (Notes 6, 10 and 11)			
Stockholders' equity (Note 7) Preferred stock - \$.01 par value; authorized, 2,000,000 shares Common stock - \$.01 par value; authorized, 20,000,000 shares;			
issued and outstanding, 3,429,402 and 1,630,450 at December 31, 1998			
and 1997, respectively Additional paid-in capital	34,000 16,000 24,906,000 20,331,000		
Deficit accumulated during the development stage	(23,145,000) (19,748,000)		
Total stockholders' equity	1,795,000 599,000		
Total liabilities and stockholders' equity	\$2,351,000 \$1,447,000		

</TABLE>

The accompanying notes are an integral part of these statements.

## F-4

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

# CONSOLIDATED STATEMENTS OF OPERATIONS

# <TABLE> <CAPTION>

	February 24,1988 (inception) to Year ended December 31, December 31,
	1998 1997 1996 1998
<s> Revenues Recearch and developmen</s>	$\begin{array}{cccccccccccccccccccccccccccccccccccc$
Total revenues	- 435,000 167,000 5,185,000
General and administrativ Depreciation and amortiza Write-off of excess purcha	nt 1,756,000 2,433,000 1,405,000 10,365,000 /e 1,464,000 1,784,000 1,938,000 8,327,000 ation 213,000 162,000 123,000 1,269,000 hase price - 580,000 8,314,000 8,894,000
Total expenses	3,433,000 4,959,000 11,780,000 28,855,000
Loss from operations	(3,433,000) (4,524,000) (11,613,000) (23,670,000)
Interest expense	is income 58,000 119,000 196,000 832,000 (22,000) (36,000) (45,000) (180,000)
	36,000 83,000 151,000 652,000
	(3,397,000) (4,441,000) (11,462,000) (23,018,000)
Provision for income taxe	es 127,000
	\$(3,397,000) \$(4,441,000)\$(11,462,000) \$(23,145,000) 
Basic and diluted loss per common share	\$(1.28)   \$(2.80)   \$(7.68)
Weighted average basic an common shares outstanding	nd diluted ng 2,650,168 1,583,785 1,492,278 ====================================

  |The accompanying notes are an integral part of these statements.

# F-5

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

# CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

<TABLE> <CAPTION>

	Deficit accumulated	
	Common stock Additional duri	-
	Shares Amount capital stage	
<s> Balance, February 24,</s>	<c> <c> <c> <c>           1988         -         \$         -         \$</c></c></c></c>	-
Common stock issued Common stock issued	1	7,000 - 2,000 -

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, \$2.18 per share       4,000       -       29,000       -         Common stock issued, \$33.00 per share       4,000       -       124,000       -         Common stock issued, \$0.20 per share       97,000       1,000       8,000       -         Net loss for the year       -       -       -       (191,000)
Balance, December 31, 1989 128,000 1,000 270,000 (221,000)
Common stock issued, \$60.00 per share 4,000       - 218,000       -         Common stock issued, \$156.40 per share 14,000       - 2,225,000       -         Net loss for the year        -       (219,000)
Balance, December 31, 1990 146,000 1,000 2,713,000 (440,000)
Common stock issued, \$60.00 per share6,000-Contribution of equipment by shareholder468,000-Net income for the year413,000
Balance, December 31, 1991 146,000 1,000 3,187,000 (27,000)
Contribution of equipment by shareholder 89,000 - Net loss for the year (859,000)
Balance, December 31, 1992 146,000 1,000 3,276,000 (886,000)
Net loss for the year (1,384,000)
Balance, December 31, 1993 146,000 1,000 3,276,000 (2,270,000)
Net loss for the year (476,000)
Balance, December 31, 1994 146,000 1,000 3,276,000 (2,746,000)

# F-6

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

# CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) - CONTINUED

<TABLE> <CAPTION>

	Deficit accumulated Common stock Additional during the paid-in development Shares Amount capital stage
<s></s>	<c> <c> <c> <c> <c> <c> <c> <c> <c> <c></c></c></c></c></c></c></c></c></c></c>
Exercise of stock optio	\$40.00 per share 1,000 \$ - \$ 50,000 \$ - ns between share 31,000 1,000 168,000 - 4,000 (1,099,000)
Balance, December 31	, 1995 182,000 2,000 3,494,000 (3,845,000)
Merger	951,000 10,000 9,991,000 -

Common stock issued, \$14.00 share Exercise of stock options/SAR's	429,000 4,000 5,499,000 -
	8,000 - 23,000 -
for consulting services -	- 344,000 -
Net loss for the year -	(11,462,000)
Balance, December 31, 1996 1,5	70,000 16,000 19,351,000 (15,307,000)
Common stock issued, \$15.00 share	
Common stock issued, \$9.20 share Warrants issued at \$12.00 and	20,000 - 192,000 -
\$18.00 per share for financial	
consulting services -	- 188,000 -
Net loss for the year -	(4,441,000)
Balance, December 31, 1997 1,6	30,000 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, \$3.50	
per share 4,000	
Warrants issued at \$4.00 per share	
for financial consulting services	
Net loss for the year -	(3,397,000)
	29,000 \$ 34,000 \$24,906,000 \$(23,145,000)

</TABLE>

The accompanying notes are an integral part of this statement.

# F-7 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

# CONSOLIDATED STATEMENTS OF CASH FLOWS

<TABLE> <CAPTION>

SCAF HOM∕			ecember 31	ary 24, 1988 , (incepti December	
	1998	1997	1996		
			<c></c>		-
Cash flows from operating	g activitie	s:			
Net loss	\$(3,397	(,000) \$(	(4,441,000)	\$(11,462,000	0) \$(23,145,000)
Adjustments to reconcile to net cash used in ope activities:	net loss				
Write off of excess pure	chase pric	e	- 580,00	0 8,314,0	00 8,894,000
Consulting expense rela warrants granted	ated to				
Research expenses relat		-	100,000	-	100,000
common stock granted Depreciation and amort	ization	213,	000 162	2,000 123	,000 1,269,000
Unearned revenue				(150,000)	
Change in operating ass and liabilities:	sets				
Accounts receivable		1,000	(1,000)	2,000	(1,000)
Prepaid expenses and					
current assets				(186,000)	
Other assets		)00 (	1,000)	(7,000) (	6,000)
Accounts payable and					
accrued expenses	()	92,000)	(244,000)	354,000	140,000
					-

# Net cash used in operating activities (3,239,000) (3,628,000) (2,668,000) (12,345,000)

Cash flows from investing activities:         Capital expenditures       (4,000)       (16,000)       (38,000)       (1,168,000)         Sales of capital equipment       9,000       6,000       -       15,000         Purchase of Tacora, net of cash acquired       -       (124,000)       -       (124,000)         Investments       (100,000)       (50,000)       -       (150,000)
Net cash used in investing activities (95,000) (184,000) (38,000) (1,427,000)
Cash flows from financing activitiesProceeds from notes payable(173,000)-118,000721,000Payments of principal on obligations-(127,000)(627,000)Cash acquired in merger with Chemex1,587,0001,587,000Proceeds from stock issuances4,556,000-5,526,00013,578,000
Net cash provided by (used in)           financing activities         4,383,000         (178,000)         7,104,000         15,259,000
Net increase (decrease) in cash and cash equivalents1,049,000(3,990,000)4,398,0001,487,000
Cash and cash equivalents at beginning of period 438,000 4,428,000 30,000 -
Cash and cash equivalents at end of period \$1,487,000 \$ 438,000 \$ 4,428,000 \$ 1,487,000 ==================================
Cash paid for interest       \$22,000       \$34,000       \$45,000       \$177,000         Cash paid for income taxes       -       -       -       127,000
Supplemental disclosure of noncash transactions Payable accrued for fixed asset purchase \$- \$- \$- \$- \$47,000 Elimination of note payable to Chemex Pharmaceuticals due to merger - 100,000 100,000 Stock issued for license on patents - 500,000 - 500,000 Equipment purchases financed through capital leases - 82,000 - 82,000 Net liabilities assumed in acquisition of Tacora Corporation - 455,000 - 455,000 

The accompanying notes are an integral part of these statements.

F-8 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Three years ended December 31, 1998

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

#### Nature of Operations

Access Pharmaceuticals, Inc. ("Access" or the "Company") is a sitedirected drug targeting company using bioresponsive carriers to target and control the release of therapeutic agents into sites of disease activity and clear the non-targeted drug-fraction. The Company operates in a single industry segment. The Company is in the development stage and its efforts have been principally devoted to research and development, resulting in significant losses since inception on February 24, 1988.

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

#### Merger

Access, formerly known as Chemex Pharmaceuticals, Inc. ("Chemex"), merged with Access Pharmaceuticals, Inc., a Texas corporation ("API"), on January 25, 1996. Shareholders of both companies approved the merger. Under the terms of the merger agreement, API was merged into Chemex with Chemex as the surviving legal entity. Chemex acquired all of the outstanding shares of API in exchange for 695,998 shares of registered common stock of Chemex, a conversion factor of 3.824251 Chemex shares for each API share. The fair value of Chemex was \$10.0 million. The excess of purchase price over the net assets acquired of \$8,313,516 was recorded and written off during the first quarter of 1996 due to an immediate impairment of the excess purchase price. Chemex also changed its name to Access Pharmaceuticals, Inc. and the operations of the merged company are now based in Dallas, Texas.

As a result of the merger and immediately after the merger, the former API Stockholders owned approximately 60% of the issued and outstanding shares of Chemex. Generally accepted accounting principles require that a company whose stockholders retain the controlling interest in a combined business be treated as the acquiror for accounting purposes. As a consequence, the merger was accounted for as a "reverse acquisition" for financial reporting purposes and API was deemed to have acquired an approximate 60% interest in Chemex. Despite the financial reporting requirement to account for the acquisition as a "reverse acquisition," Chemex remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes.

#### Principles of Consolidation

The consolidated financial statements include the financial statements of Access Pharmaceuticals, Inc. and Tacora Corporation, a wholly-owned subsidiary. All significant intercompany balances have been eliminated in consolidation.

F-9 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

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

Cash and Cash Equivalents

The Company considers 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. Cash and cash equivalents consist primarily of cash in banks and money market funds.

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

The Company expenses patent and application costs as incurred because, even though the Company believes the patents and underlying processes have continuing value, the amount of future benefits to be derived therefrom are uncertain.

### Licenses

The Company recognizes the purchase value of licenses and amortizes them over the estimated useful lives. The Company acquired a license to certain patents for \$500,000 by issuing 40,000 shares of the Company's common

stock in 1997. The license is amortized over ten years. Amortization was \$50,000 and \$25,000 for the years ended December 31, 1998 and 1997, respectively.

#### **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. 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.

F-10 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

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

#### Income Taxes

Tax credits related to research and development and to investments in equipment and improvements are reported as a reduction of income tax expense in the year realized. 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" ("SFAS No. 128"), the Company has 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.

#### Use of Estimates

Management of the Company has made a number of estimates and assumptions relative to the reporting of assets and liabilities 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.

# Reclassifications

Certain reclassifications have been made to prior year financial statements to conform with the December 31, 1998 presentation.

# F-11

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

#### Three years ended December 31, 1998

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

# Stock Option Plans

Prior to January 1, 1996, the Company accounted for its 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 would be recorded on the day of grant only if the current market price of the underlying stock exceeded the exercise price. On January 1, 1996, the Company adopted Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, which permits entities to recognize as expense over the vesting period the fair value of all stock-based awards on the date of grant. Alternatively, SFAS No. 123 also allows entities to continue to apply the provisions of APB Opinion No. 25 and provide pro forma net income (loss) and pro forma earnings (loss) per share disclosures for employee stock option grants made in 1995 and future years as if the fair-value-based method defined in SFAS No. 123 had been applied. The Company has elected to continue to apply the provisions of ABP Opinion No. 25 and provide the pro forma disclosure provisions of SFAS No. 123.

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 current assets and current liabilities approximates fair value due to the short maturity of these items.

### F-12

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

#### NOTE 2 - ACQUISITIONS

On December 9, 1997, a wholly-owned subsidiary of the Company acquired and merged with Tacora Corporation ("Tacora"), a privately-held pharmaceutical company based in Seattle, Washington; Tacora became a wholly-owned subsidiary of the Company. The Company used the purchase method of accounting for the purchase of Tacora. 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, plus up to 137,500 shares of additional Common Stock if certain milestones are met. The share price to be used will range between \$2.50 and \$6.50 per share (range of value of shares is \$344,000 to \$894,000), depending on when the milestones are met. All milestone conditions expire in June 2000. The aggregate purchase price has been allocated to the net assets acquired based on management's estimates of the fair values of assets acquired and liabilities assumed. The excess purchase price over the fair value of Tacora's net identifiable assets of \$579,544 was recorded and written off in the fourth quarter of 1997 due to an impairment of the excess purchase price based on estimated future cash flows. Operations have been included in the Company's consolidated financial statements since the date of acquisition. Pro forma disclosure relating to the Tacora acquisition is not presented as the impact is immaterial to the Company.

#### NOTE 3 - RELATED PARTY TRANSACTIONS

Under consulting agreements between Thoma Corporation ("Thoma") and the Company, Thoma receives payments for consulting services and reimbursement of direct expenses. Herbert H. McDade, Jr., the Chairman of the Board of Directors of the Company, is an owner of Thoma Corp. During 1998, 1997 and 1996 Thoma received payments for consulting services of \$72,000, \$72,000 and \$60,000 respectively. Thoma was also reimbursed for expenses of \$11,000, \$6,000, and \$18,000 respectively, in 1998, 1997 and 1996.

Stephen B. Howell, M.D., Director of the Company receives payments for consulting services and reimbursement of direct expenses. Dr. Howell consulted with the Company in 1998 and 1997 and received \$8,000 and \$2,000 in consulting fees and \$4,000 and \$1,000 in expense reimbursements, respectively.

Under the terms of the "Patent Purchase Agreement" dated April 5, 1994, as amended on January 23, 1996 between Dr. David F. Ranney and the Company, Dr. Ranney, a major shareholder of the Company, was entitled to yearly cash royalty payments as consideration for the assignment of patents to the Company. A royalty of \$52,500 and \$50,000 was payable at December 31, 1997 and 1996, respectively, and included in the accompanying consolidated balance sheet. Dr. Ranney signed an agreement whereby all rights, title and interest in and to all inventions and confidential information became the sole and exclusive property of the Company as of May 31, 1998.

F-13 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

#### NOTE 4 - RESEARCH AND DEVELOPMENT AGREEMENTS

On August 1, 1997, the Company entered into an agreement with The Dow Chemical Company ("Dow Chemical") for the development of products incorporating Dow Chemical's chelation technology and Access' Bio=Responsive TM polymer systems. The collaboration will focus on the development of MRI contrast agents and radiopharmaceutical diagnostics and therapeutics. The advancement of the Access developments in these areas are dependent on securing chelation technology, which encapsulates metals to avoid adverse effects on the body.

The Company entered into a technology evaluation option agreement with a pharmaceutical company. The Company recognized revenue under the agreement as certain milestones were achieved and amounted to \$110,000 and \$165,000 in 1997 and 1996, respectively. Proceeds received in excess of amounts recognized were accounted for as unearned income. This agreement was terminated March 29, 1996.

Property and equipment consists of the following: <TABLE> <CAPTION>

CAI HOW	December 31,			
	1998	1997		
<s></s>	<c></c>	<c></c>		
Laboratory equipment		\$ 808,000	\$ 852,000	
Laboratory and building impre	ovements	27	,000 25,000	
Furniture and equipment		172,000	170,000	
	1,007,00	0 1,047,00	00	
Less accumulated depreciation	n and amo	ortization	780,000 625,000	
Net property and equipment		\$ 227,00	0 \$ 422,000	

  |  |  |Depreciation and amortization on property and equipment was \$161,000, \$137,000, and \$123,000 for the years ended December 31, 1998, 1997 and 1996, respectively.

F-14

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

# NOTE 6 - COMMITMENTS

At December 31, 1998, future minimum lease payments under capital lease obligations and commitments under noncancelable operating leases were as follows:

<TABLE> <CAPTION>

<caption></caption>	
	Capital Operating
	leases leases
<s></s>	<c> <c></c></c>
1999	\$ 107,000 \$ 82,000
2000	25,000 87,000
2001	- 91,000
2002	- 85,000
Total future minimum lease p	ayments 132,000 \$ 345,000
Less amount representing inte	erest 9,000 ======
Present value of minimum car	pital lease payments 123,000
Less current portion	99,000
Obligations under capital leas	ses,
excluding current portion	\$ 24,000

  ||  |  |
The Company leases certain office and research and development facilities under an operating lease. Rent expense for the years ended December 31, 1998, 1997 and 1996 was \$77,000, \$74,000 and \$69,000, respectively.

NOTE 7 - STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

On June 18, 1998, in conjunction with the first closing of a private placement, the Company effected a recapitalization through a one-fortwenty reverse stock split of its common stock, \$0.04 par value per share (the "Common Stock"), and decreased the number of authorized shares of Common Stock from 60.0 million, at \$0.04 par value per share, to 20.0 million shares, \$0.01 par value per share, and decreased the authorized shares of preferred stock of the Company from 10.0 million to 2.0 million (the "Recapitalization"). The Recapitalization decreased the number of outstanding shares of Common Stock from approximately 41.5 million to 2.1 million.

All share and per share amounts have been retroactively restated to reflect the Recapitalization in the accompanying consolidated financial statements.

F-15 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

#### NOTE 7 - STOCKHOLDERS' EQUITY (DEFICIT) - Continued

The Company, assisted by an investment bank, raised in March and April of 1998, \$1,200,000 in gross proceeds less cash issuance costs of \$47,000, from the placement of 48 units, each unit consisting of 8,333 shares of Common Stock (total of 399,984) and warrants to purchase 8,333 shares of Common Stock (total of 399,984) at an exercise price of \$3.00 per share. The placement agent received warrants to purchase 44,527 shares of Common Stock at \$3.00 per share, in accordance with the offering terms and elected to receive 45,277 shares of Common Stock in lieu of certain sales commissions and expenses.

On June 18, 1998, the Company, assisted by the same investment bank, raised an aggregate of \$2.9 million in gross proceeds, less cash issuance costs of \$202,000, from the first closing of a private placement of 953,573 shares Common Stock at \$3.00 per share. The placement agent for such offering received warrants to purchase 101,653 shares of Common Stock at \$3.00 per share, in accordance with the offering terms and elected to receive 62,949 shares of Common Stock in lieu of certain sales commissions and expenses.

On July 30, 1998, the Company, assisted by the same investment bank, raised an aggregate of \$900,000 in gross proceeds, less cash issuance costs of \$24,000, from the second closing of a private placement of 300,000 shares of Common Stock at \$3.00 per share. The placement agent for such offering received warrants to purchase 33,445 shares of Common Stock at \$3.00 per share, in accordance with the offering terms and elected to receive 34,450 shares of Common Stock in lieu of certain sales commissions and expenses. The proceeds of the offering will be used to fund research and development, working capital, acquisitions of complementary companies or technologies and general corporate purposes.

For 1998, issuance costs for all placements totaled \$1,466,000, consisting of \$405,000 cash payments for offering and legal expenses and the issuance of 142,676 shares of Common Stock valued at \$385,000 and 179,625 warrants with a fair value of \$676,000 calculated using the Black-Scholes pricing model. The proceeds of the offerings will be used to fund research and development, working capital, acquisitions of complementary companies or technologies and general corporate purposes.

The investment bank has been engaged to assist the Company in raising additional capital to fund research and development, working capital, acquisitions of complementary companies or technologies and general corporate purposes. There can be no assurances, however, that any additional funds will be raised. During 1998, a financial advisor received warrants to purchase 15,000 shares of common stock at an exercise price of \$4.00 per share 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.

F-16

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

#### NOTE 7 - STOCKHOLDERS' EQUITY (DEFICIT) - Continued

In connection with the aforementioned 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.

During 1997, a financial advisor received warrants to purchase 37,500 shares of common stock, one-half (18,750 shares) at an exercise price of \$12.00 per share, and one-half (18,750 shares) at an exercise price of \$18.00 per share any time from January 1, 1998 until June 30, 2002, for financial consulting services rendered in 1997. The fair value of the warrants was \$5.00 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 5.6%, expected volatility 129% and an expected life of 5 years. Total fair value of the warrants relating to the consulting services (\$188,000) has been recorded as general and administrative expense and an increase to additional paid-in capital.

During 1996, a shareholder received warrants to purchase 30,000 shares of common stock at an exercise price of \$20.00 per share any time from March 5, 1997 until March 4, 2000, for compensation for consulting services. The fair value of the warrants was \$15.40 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 6.1%, expected volatility 100% and an expected life of 3 years. The portion of the total fair value of the warrants relating to the consulting services (\$344,000) has been recorded as general and administrative expense and an increase to additional paid-in capital.

On October 5, 1995, the Company entered into an agreement with a shareholder for the sale of 2,390 units. Each unit consisted of one share of common stock and a warrant to purchase one-half share of common stock. The exercise price for the warrants is \$3.00 per share. The warrants are exercisable until October 5, 1999.

The Company also has warrants outstanding to purchase 6,795 shares of common stock at \$3.00 per share. These warrants expire in September 2001. Units consisting of an option to purchase 25,000 shares of common stock and warrants to purchase 35,000 shares of common stock at prices ranging from \$50 to \$125 per share expired in January 1999.

# F-17 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

Three years ended December 31, 1998

#### NOTE 8 - STOCK OPTION PLANS

The Company adopted a new stock option plan, as amended (the "1995 Stock Awards Plan"), on January 25, 1996 and reserved 548,271 shares of the Company's authorized but unissued common stock for issuance to optionees including officers, employees, and other individuals performing services for the Company. The 1995 Stock Awards Plan replaced the previously approved stock option plan (the "1987 Stock Awards Plan") and API's stock option plan ("API Stock Option 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. However, as a result of certain events occurring in 1995, all granted options in the 1987 Stock Awards Plan became vested and exercisable and all options in the API Stock Option Plan were exercised or forfeited. No further grants have been or can be made under the 1987 Stock Awards Plan, and the API Stock Option Plan has been canceled. New stock options are generally granted with an exercise price equal to the stock's quoted market value at the date of grant.

At December 31, 1998, there were 241,771 additional shares available for grant under the 1995 Stock Awards Plan. Concurrently with the Recapitalization on June 18, 1998, all stock options granted under the 1995 Stock Option Plan were cancelled and new stock options were issued to directors, employees and consultants. 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 1998, 1997 and 1996, respectively: dividend yield of 0% for all periods; volatility of 122%, 129%, and 100%; risk-free interest rates of 4.84%, 5.6% and 6.0% and expected lives of four years for all periods. The weighted average fair values of options granted were \$2.40, \$13.00 and \$18.40 per share during 1998, 1997 and 1996, respectively.

The Company applies APB Opinion No. 25 in accounting for its 1995 Stock Awards Plan. 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 the Company determined compensation cost based on the fair value at the grant date for its stock options under SFAS No. 123, the Company's net loss and loss per share would have been reduced to the pro forma amounts indicated below:

#### <TABLE> <CAPTION>

</TABLE>

	D			
	1998	1997	1996	-
<s></s>	<c></c>	<c></c>	<c></c>	
Net loss				
As reported	\$(3,39	97,000) \$(	4,441,000	) \$(11,462,000)
Pro forma	(3,58)	3,000) (4,	,614,000)	(11,563,000)
Basic and diluted	loss per share			
As reported	(\$1	1.28) (9	\$2.80)	(\$7.68)
Pro forma	(\$1	.35) (\$	(2.91)	(\$7.75)

F-18 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

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

#### <TABLE> <CAPTION>

<cap hon=""></cap>	Weigh averag exerci Shares pr	ge se	
<s></s>	<c> &lt;</c>	< <u>C</u> >	
Outstanding options at January Granted Forfeited	1, 1996 33,299 (1,800)		-
Outstanding options at Decemb	per 31, 1996	31,499	26.20
Granted Forfeited	8,217 (7,566)	13.00 (27.60)	
Outstanding options at Decemb	per 31, 1997	32,150	20.40
Granted Forfeited	306,500 (32,150)	3.00 (20.40)	
Outstanding options at Decemb	ber 31, 1998	306,500	0 3.00
Exercisable at December 31, 19 Exercisable at December 31, 19 Exercisable at December 31, 19	997	8,950 142,500	25.60 3.00

# </TABLE>

At December 31, 1998, the exercise price of 302,000 options was \$3.00, of 3,500 options was \$2.94 and of 1,000 options was \$2.08. The weighted-average remaining life was 9.5 years.

F-19 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

# NOTE 8 - STOCK OPTION PLANS - Continued

All issued options and stock appreciation rights ("SAR's") under the Chemex 1987 Stock Awards Plan became vested and exercisable due to the merger on January 25, 1996. No further grants can be made. Summarized information for the 1987 Stock Awards Plan is as follows:

<TABLE> <CAPTION>

	1987 Non- Weighted-	
	Incentive Employee Average	
	Stock Director Exercise	
	Options SAR's Plan Price	
<s></s>		
<c></c>		
Outstanding awards at	January 1, 1996 48,804 16,933 13,956 \$39.	.80
Forfeited	(7,569) - (5,046) 51.40	
Exercised	(1,371) (6,736) - 3.00	

Outstanding awards at December 31, 1996 39,864 10,197 8,910 40.80

 Forfeited
 (1,125)
 (3,660)
 72.40

 Outstanding awards at December 31, 1997
 38,739
 10,197
 5,250
 38.00

 Forfeited
 (6,153)
 (2,500)
 (2,750)
 (47.75)

 Outstanding awards at December 31, 1998
 32,586
 7,697
 2,500
 35.49

</TABLE>

All options outstanding were exercisable at each year end.

Further information regarding options outstanding at December 31, 1998 is summarized below:

<TABLE> <CAPTION>

W	ei	gh	te	d	av	ve	ra	ıge
								-

	Number of	Remain	ning E	xercise
Range of exercise pr	ices o	f shares	life	price
<s></s>	<c></c>	<c></c>	<c></c>	
\$0.0	7,700	4.68	\$ 0.0	00
\$17.50 - \$35.00	21,	128	5.10	23.85

0.00 - \$64.40	7,081	1.85	47.41
8.80 - \$102.60	6,874	4.00	98.71
4	2,783		
==			

#### </TABLE>

\$4 \$7

F-20

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

# NOTE 9 - INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

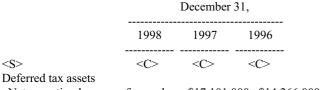
<TABLE>

<caption></caption>	1998	1997	1996	
<s> Income taxes at U.S. sta Change in valuation allo Items not deductible for</s>	wance	<c> \$(1,155,0 1,142,00 13,000</c>		,
Total tax expense	\$	- \$	- \$ -	

</TABLE>

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

<TABLE> <CAPTION>



Net operating loss carryforwards \$17,101,000 \$14,266,000 \$13,107,000

ryforwards	443,000	) 43	4,000	408,000
24	1,000	-	-	
17,56	8,000 1	4,700,0	00 13	,515,000
(17,56	8,000) (1	4,700,0	00) (13	,515,000)
\$ -	\$ -	\$	-	
	24 17,56 (17,56	24,000 17,568,000 1 (17,568,000) (1	24,000 - 17,568,000 14,700,0 (17,568,000) (14,700,0	24,000 17,568,000 14,700,000 13 (17,568,000) (14,700,000) (13

</TABLE>

During 1998, the Company's gross deferred tax asset increased by \$2,612,000 due to losses and a restatement of prior years' net operating loss carryforwards of approximately \$1,470,000. The valuation allowance was increased by a corresponding amount.

At December 31, 1998, the Company had approximately \$50,700,000 of net operating loss carryforwards and approximately \$1,300,000 of general business carryforwards. These carryforwards expire at varying amounts through 2013. As a result of the 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 related to Chemex to approximately \$530,000 per year.

F-21

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

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

# NOTE 10 - CONTINGENCIES

The Company's products will require clinical trials, U.S. Food and Drug Administration approval, or approval of similar authorities internationally and acceptance in the marketplace prior to commercialization. Although the Company believes its patents and patent applications are valid, the invalidation of its major patents would have a material adverse effect upon its business. The Company competes with specialized biotechnology companies and major pharmaceutical companies. Many of these competitors have substantially greater resources than the Company.

The Company is not currently a party to any material legal proceeding.

# NOTE 11 - LIQUIDITY

The Company has incurred negative cash flows from operations since its inception, and has expended, and expects to continue to expend in the future, substantial funds to complete its planned product development efforts. The Company expects that its existing capital resources will be adequate to fund the Company's operations through the second quarter of 1999. The Company is dependent on raising additional capital to fund its development of technology and to implement its business plan. Such dependence will continue at least until the Company begins marketing its new technologies.

If the anticipated revenues are delayed or do not occur, or the Company is unsuccessful in raising additional capital on acceptable terms, the Company would be required to curtail research and development and general and administrative expenditures so that working capital would cover reduced operations into the third quarter of 1999. There can be no assurance, however, that changes in the Company's operating expenses will not result in the expenditure of such resources before such time.

The Company will require substantial funds to conduct research and development programs, preclinical studies and clinical trials of its potential products. The Company's 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 for research, development and commercialization of products with corporate partners; continued scientific progress in the Company's 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 and, the ability to establish and maintain effective commercialization activities and arrangements.

The Company intends to seek additional funding through research and development or licensing arrangements with potential corporate partners, public or private financing, or from other sources. The Company does not have any committed sources of additional financing and there can be no assurance that additional financing will be available on favorable terms, if at all. In the event that adequate funding is not available, the Company may be required to delay, reduce or eliminate one or more of its research or development programs or obtain funds through arrangements with corporate collaborators or others that may require the Company to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than the Company would otherwise seek. Insufficient financing may also require the Company to relinquish rights to certain of its technologies that the Company would otherwise develop or commercialize itself. If adequate funds are not available, the Company's business, financial condition and results of operations will be materially and adversely effected.

> F-22 Access Pharmaceuticals, Inc. and Subsidiary (a development stage company)

# NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - CONTINUED

Three years ended December 31, 1998

#### NOTE 12 - SUBSEQUENT EVENTS

On March 1, 1999, the Company and a wholly owned subsidiary of the Company entered into a merger agreement with Virologix Corporation ("Virologix"), whereby Virologix will become a wholly owned subsidiary of the Company. The closing of the merger is subject to certain conditions, including the condition that the Company raise at least \$3.0 million in equity financing.

Virologix is a privately held company focused on the development of product candidates for the prevention and treatment of viral diseases, including HIV. Under the terms of the agreement, the Virologix shareholders will receive 1,000,000 shares of common stock of the Company. It is anticipated that the closing of the acquisition will take place during the second quarter of 1999.

F-23

# EXHIBIT 10.17

# Agreement

Between

Access Pharmaceuticals, Inc.

And

# Block Drug Company, Inc.

12/17/98

12/11/90		
ARTICLE 1 DEFINITIONS	1	
1.1 Access	1	
1.1 Access 1.2 Access Know-How	2	
1.3 Cumulative Worldwide Net Sales	2 2	
1.4 Affiliate	3	
1.5 Amlexanox	3	
1.6 Block	3	
1.7 Block-Chemex Agreement	3	
1.8 Block Know-How	4	
1.9 Oral Mucositis Use/Mucositis Indication	•	
1.10 Effective Date	5	
1.11 First Sale	5	
1.12 Non-Licensed Indication Improvement		
1.13 Oral Mucositis Use/Mucositis Indicatio		
1.14 Licensed Patents	5	
1.15 Notice	6	
1.16 Product	6	
1.17 Takeda	6	
1.18 Takeda License Agreement	6	
1.19 Takeda Sublicensed Patents	6	
1.20 Takeda Supply Agreement	6	
1.21 Term	6	
1.22 Territory	7	
1.23 Sublicensee Net Sales	, 7	
1.24 Block Patent	7	
1.2 T Dioek I dent	,	
ARTICLE 2 GRANT	7	
2.1 Grant	8	
2.1 Glain	0	
ARTICLE 3 ACCESS ROYAL TIES/MIL	ESTONE PAYMENTS	8
ARTICLE 3 ACCESS ROYALTIES/MII		8
3.1 Milestone Payments	8	8
<ul><li>3.1 Milestone Payments</li><li>3.2 Payment Schedule</li></ul>	8 8	8
<ul><li>3.1 Milestone Payments</li><li>3.2 Payment Schedule</li><li>3.3 Royalty Payments</li></ul>	8 8 10	8
<ul><li>3.1 Milestone Payments</li><li>3.2 Payment Schedule</li><li>3.3 Royalty Payments</li><li>3.4 Quarterly Royalty Reports</li></ul>	8 8 10 11	8
<ul><li>3.1 Milestone Payments</li><li>3.2 Payment Schedule</li><li>3.3 Royalty Payments</li></ul>	8 8 10	8
<ul><li>3.1 Milestone Payments</li><li>3.2 Payment Schedule</li><li>3.3 Royalty Payments</li><li>3.4 Quarterly Royalty Reports</li><li>3.5 Payment of Royalties</li></ul>	8 8 10 11 12	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> </ul> ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLICAL OBLI	8 8 10 11 12 ONS OF THE PARTIES	8
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLICAL O</li></ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL Access to Pay Registration Fees and Co</li> <li>4.2 Access to Pay Takeda Royalties to Bloc</li> </ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLICAL O</li></ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL Access to Pay Registration Fees and Co</li> <li>4.2 Access to Pay Takeda Royalties to Bloc</li> <li>4.3 Access to Provide Data</li> </ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> </ul> ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL Access to Pay Registration Fees and Co 4.2 Access to Pay Takeda Royalties to Bloc 4.3 Access to Provide Data	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12 12	
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<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OP AND A CONTROL OF AND A CONTROL OF A CO</li></ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12 k 12 12 RIGHTS AND OBLIGATIONS 13	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OB</li></ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12 12 RIGHTS AND OBLIGATIONS 13 DN 13	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OB</li></ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12 12 RIGHTS AND OBLIGATIONS 13 DN 13	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIG</li> <li>4.1 Access to Pay Registration Fees and Co</li> <li>4.2 Access to Pay Takeda Royalties to Block</li> <li>ARTICLE 5 BLOCK IMPROVEMENT</li> <li>5.1 Grant Rights to Block</li> <li>ARTICLE 6 TERM AND TERMINATIO</li> <li>6.1 Term</li> <li>6.2 Termination for Breach</li> </ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12 12 RIGHTS AND OBLIGATIONS 13 DN 13 13 13 13	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OB</li></ul>	$ \begin{array}{c} 8\\ 8\\ 10\\ 11\\ 12\\ \end{array} $ ONS OF THE PARTIES sts 12 k 12\\ 12\\ \end{array}  RIGHTS AND OBLIGATIONS 13 DN 13 13 13 13 13	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OP AND TERMINATIONAL OP AND TERMINAL OP AND TERMINATIONAL OP AND TERMINAL OP AND</li></ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12 12 RIGHTS AND OBLIGATIONS 13 DN 13 13 13 0 Pay Takeda	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OP Payment of Payment</li></ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12 12 RIGHTS AND OBLIGATIONS 13 DN 13 13 13 0 Pay Takeda 15	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OP Payment of Payme</li></ul>	$ \begin{array}{c} 8\\ 8\\ 10\\ 11\\ 12\\ \end{array} $ ONS OF THE PARTIES sts 12 k 12\\ 12\\ \end{array}  RIGHTS AND OBLIGATIONS 13 DN 13 13 0 Pay Takeda 15 ent or Takeda	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OP Payment of Payment</li></ul>	8 8 10 11 12 ONS OF THE PARTIES sts 12 k 12 12 RIGHTS AND OBLIGATIONS 13 DN 13 13 13 0 Pay Takeda 15	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> </ul> ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OBLIGATIONAL OP Payment of Payment Payment Payment OP Payment	$ \begin{array}{c} 8\\ 8\\ 10\\ 11\\ 12\\ \end{array} $ ONS OF THE PARTIES sts 12 k 12\\ 12\\ RIGHTS AND OBLIGATIONS 13\\ 0N 13\\ 13\\ 13\\ 0 Pay Takeda 15\\ ent or Takeda 15\\ \end{array}	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONALO OBLIGATIONALO</li></ul>	$ \begin{array}{c} 8\\ 8\\ 10\\ 11\\ 12\\ \end{array} $ ONS OF THE PARTIES sts 12 k 12\\ 12\\ RIGHTS AND OBLIGATIONS 13 0N 13 13 0N 13 13 0 Pay Takeda 15 ent or Takeda 15 16\\ \end{array}	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATION OF BEACH 6.3 Rights to Survive</li> <li>6.4 Reversion and Termination for Failure the License Fees</li> <li>6.5 Termination of Takeda Supply AgreemonAlicense Agreement</li> <li>ARTICLE 7WARRANTIES</li> <li>7.1 Exploitation of Licensed Rights</li> </ul>	$ \begin{array}{c} 8\\ 8\\ 10\\ 11\\ 12\\ \end{array} $ ONS OF THE PARTIES sts 12 k 12\\ 12\\ RIGHTS AND OBLIGATIONS 13 0N 13 13 0N 13 13 0 Pay Takeda 15 ent or Takeda 15 16 16 16 16 10	
<ul> <li>3.1 Milestone Payments</li> <li>3.2 Payment Schedule</li> <li>3.3 Royalty Payments</li> <li>3.4 Quarterly Royalty Reports</li> <li>3.5 Payment of Royalties</li> <li>ARTICLE 4 ADDITIONAL OBLIGATIONAL OBLIGATIONALO OBLIGATIONALO</li></ul>	$ \begin{array}{c} 8\\ 8\\ 10\\ 11\\ 12\\ \end{array} $ ONS OF THE PARTIES sts 12 k 12\\ 12\\ RIGHTS AND OBLIGATIONS 13 0N 13 13 0N 13 13 0 Pay Takeda 15 ent or Takeda 15 16\\ \end{array}	

13

<ul><li>7.4 Obligations Regarding Patent Infringen</li><li>7.5 Claims by Third Parties</li><li>7.6 No Restrictions on Product</li></ul>	nent 17 18 18
7.7 Power to Enter Into Agreement	18
7.8 No Other Warranties or Representations	
7.9 Warranties of Block	19
7.5 Warranties of Block	19
ARTICLE 8 MISELLANEOUS	21
8.1 New Jersey Law Applies	21
8.2 Alternative Dispute Resolution	21
8.3 No Agency or Employment	23
8.4 Notice	23
8.5 Severability	25
8.6 Entire Agreement/Merger	25
8.7 Amendment	26
8.8 Counterparts	26
8.9 No Waiver of Rights	26
8.10 Force Majeure	26
8.11 Further Assurances	27
8.12 Audit Rights	27
8.13 Binding Effect	27
8.14 No Strict Construction	27
8.15 Consent Not Unreasonably Withheld of	or Delayed 28
8.16 Bankruptcy	28
8.17 Assignment	28
8.18 Taxes	28
8.19 Cooperation on Publicity	29
8.20 Costs of Agreement	29
8.21 Headings For Convenience Only	29
, and get the second	
ii	
8.22 Independent Contractor	30
8.23 No Finder's Fee	30
8.24 Notification of Infringement	30
8.25 References	30
8.26 Singular and Plural	31
8.27 Successors and Assigns	31
8.28 Validity and Severability	31
8.29 Waiver	31
8.30 Takeda Agreements Controlling	31

ARTICLE 9 -- TAKEDA APPROVAL AND SUPPLY OF RAW MATERIAL329.1 Takeda Approval329.2 Takeda Supply of Raw Material32

iii

This Agreement, dated this 21st day of December, 1998, is by and between Block Drug Company, Inc., 257 Cornelison Avenue, Jersey City, New Jersey 07302 ("Block") and Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207 ("Access").

WHEREAS Block has certain rights in and to a topical products containing Amlexanox;

WHEREAS Access wishes to develop such products itself for the treatment of oral mucositis, as defined herein, in various countries and to seek partners in various countries to develop such product;

NOW THEREFORE, in consideration of the following mutual promises and obligations and intending to be legally bound, the parties agree as follows:

#### ARTICLE 1--DEFINITIONS

1.1 Access: means Access Pharmaceuticals, Inc. The term "Access" shall, as required by the circumstances, also mean and include any company or business entity that controls or is controlled by, either directly or indirectly, Access Pharmaceuticals, Inc., its officers, agents and employees or any partnership or joint venture in which Access Pharmaceuticals, Inc. is a participant or any company or business entity that is under common control with Access Pharmaceuticals, Inc. The term "control" means the power to direct the affairs of such entity by reason of ownership more than fifty

percent (50%) of such entity by voting stock, equity interest, contract or otherwise.

1.2 Access Know-How: means (a) any and all information in the possession of Access at any time during the Term of this Agreement which Access has the right to license or sublicense relating to the physical and chemical analysis and stability of the Product, its clinical effects and indications for use, and (b) any and all information in the possession of Access as of the date of execution of this Agreement which Access has the right to license or sublicense relating to the method of use, packaging, formulation, or method of administration of the Product that, at the time it is communicated to Block, was not rightfully in Block's possession and was not common general knowledge. Information relating to Takeda's process of manufacture of Amlexanox shall be excluded from the scope of Access Know-How.

1.3 Cumulative Worldwide Net Sales: For purposes of determining compensation to Block for Cumulative Worldwide Net Sales of Access under Paragraph 3.3 of this Agreement, "Cumulative Worldwide Net Sales" means gross revenues received by Access on the sale of the Product less (a) trade discounts actually allowed; and (b) when borne by Access in connection with the sale, transportation and handling charges; sales, use and excise taxes; import duties, tariffs or other governmental charges; and credits for claim or allowances, retroactive price reductions, refunds; returns, and recalls. There shall not be any imputed gross revenue for samples, free goods or marketing programs whereby the Product is given away to induce sales thereof. For purposes of determining Cumulative Worldwide Net Sales, a sale shall be deemed to have occurred when sale is invoiced or when the Product is delivered, whichever occurs first. In the case of the transfer or sale of Product by Access to an affiliate, distributor, or subdistributor of Access for sales by affiliate, distributor or subdistributor, Cumulative Worldwide Net Sales shall be based upon the

#### 2

greater of the total invoice price charged by Access to such affiliate, distributor or subdistributor the total invoice price charged by such affiliate, distributor or subdistributor to its customers, Cumulative Worldwide Net Sales for countries outside the U.S. shall be calculated by converting to U.S. currency using the exchange rate in effect on the last business day of each month as published in the Wall Street Journal. Cumulative Worldwide Net Sales shall also include Sublicense Net Sales as defined herein at 1.23.

1.4 Affiliate: means any corporation or business entity controlled by, controlling, or under common control with Access or Block, respectively. For this purpose, "control" shall mean the direct or indirect beneficial ownership of more than fifty percent (50%) of the voting stock, or more than a fifty percent (50%) interest in the income of such corporation or other business entity, or such other relationship as, in fact, constitutes actual control.

1.5 Amlexanox: means 2 - amino - 7 - isopropyl - 5 - oxo - 5H - [1] benzopyrano - [2,3 - 1] pyridine - 3 - carboxylic acid (Takeda Code No. AA-673).

1.6 Block: means Block Drug Company, Inc.

1.7 Block-Chemex Agreement: means that asset purchase and royalty agreement between

Block Drug Company, Inc. and Chemex Pharmaceuticals, Inc., dated as of June 7, 1995.

3

1.8 Block Know-How: means (a) any and all information in the possession of Block at any time during the Term of this Agreement which Block has the right to license or sublicense relating to the physical and chemical analysis and stability of the Product, its clinical effects and indication for use, and (b) any and all information in the possession of Block as of the date of execution of this Agreement which Block has the right to license or sublicense relating to the method of use, packaging, formulation, or method of administration of the Product that, at the time it is communicated to Access, was not rightfully in the possession of Access and was not common general knowledge. Information relating to Takeda's process of manufacture of Amlexanox shall be excluded from the scope of Block Know-How. 1.9 Oral Mucositis Use/Mucositis Indication: means solely the treatment of chemotherapy or radiation-induced inflammation of the oral mucous membrane and inflammation of the oral mucous membrane in immuno compromised patients. By way of further clarification, Access hereby is granted no Amlexanox rights whatsoever under this Agreement for any other uses for any patients whether or not they are immuno compromised including, but not limited to, the following treatments gingivitis, periodontitis, aphthous ulcers, chronic atrophic senile mucositis and fusospirohetal mucositis. The parties acknowledge Access has rights to develop, sell and license Amlexanox under the Block Access Agreement.

1.10 Effective Date: means the date first set forth above.

1.11 First Sale: means the date on the first invoice to any customer purchasing commercial

#### 4

quantities of Product or an Improvement on a country by country basis after the Effective Date of this Agreement.

1.12 Non-Licensed Indication Improvements: means all inventions, developments improvements, whether or not patentable, both for prescription and non-prescription indications for Amlexanox originated or acquired by Access other than those related to the Oral Mucositis Use/Mucositis Indication, which is the subject of this Agreement, and other than those related to the Block Chemex Agreement or the Block Access Agreement.

1.13 Oral Mucositis Use/Mucositis Indication Improvements: means all inventions, developments or improvements, whether or not patentable, both for prescription and non-prescription indications originated or acquired by Access for the Oral Mucositis Use/Mucositis Indication which is the subject of this Agreement.

1.14 Licensed Patents: means all patents and applications and any continuation-in-part, continuation or division thereof, or substitute thereof set forth in Exhibit B of the agreement between Block and Access dated March 5, 1998 (the "Block Access Agreement") and Schedule l.l(b)(i) of the Block Chemex Agreement and all Takeda Sublicensed Patents.

1.15 Notice: shall have the meaning set forth in Paragraph 8.4 hereof. "Notify" shall mean to provide Notice in accordance with Paragraph 8.4 hereof.

#### 5

1.16 Product: means any topical formulation containing Amlexanox for Oral Mucositis Use/Mucositis Indication which Access develops, excluding any formulation as described in the Block Access Agreement or the Block Chemex Agreement.

1.17 Takeda: means Takeda Chemical Industries, Ltd., a Japanese corporation and all parents, subsidiaries and affiliates thereof.

1.18 Takeda License Agreement: means that agreement between Chemex and Takeda dated November 12, 1987 regarding licensing of patent rights from Takeda to Chemex. A copy of that agreement is set forth in Exhibit C of the Block Access Agreement.

1.19 Takeda Sublicensed Patents: means any and all patent applications and patents now or hereafter owned or controlled by Takeda in the Territory relating to the Product, including any and all patents issuing or maturing from such patent applications, or any reissue application, divisions, extensions, Improvements, and continuations-in-part thereof. Such current Takeda Patents and patent applications in the Territory are listed in Exhibit D of the Block Access Agreement.

1.20 Takeda Supply Agreement: means that agreement between Chemex and Takeda dated November 12, 1987 regarding supply of material from Takeda to Chemex. A copy of that agreement is set forth in Exhibit E of the Block Access Agreement.

1.21 Term: means the term of this Agreement, as set forth in Article 6 hereof.

1.22 Territory: means all countries in the world except where Block has granted rights under the Takeda License Agreement and the Takeda Supply Agreement to Takeda which includes Japan.

1.23 Sublicensee Net Sales: means gross revenues received by the sublicensee on the sale of any Product less (a) trade discounts actually allowed; and (b) when borne by the sublicensee connection with the sale, transportation and handling charges; sales, use and excise taxes; import duties, tariffs or other governmental charges; and credits for claim or allowances, retroactive price reductions, refunds, returns, and recalls. There shall not be any imputed gross revenue for samples free goods or other marketing programs whereby the Product is given away to induce sales there of. For purposes of determining Net Sales, a sale shall be deemed to have occurred when the sale is invoiced or when the Product is delivered, whichever occurs first. In the case of the transfer or sale of Product by the sublicensee to an affiliate, distributor or subdistributor of the sublicensee for sales by such affiliate, distributor or subdistributor, Net Sales shall be based upon the greater of the total invoice price charged by the sublicensee to such affiliate, distributor or subdistributor or the tl invoice price charged by such affiliate, distributor or subdistributor to its customers.

1.24 Block Patent: means U.S. Patent 5,362,737 Methods of Treating Aphthous Ulcers and Other Mucocutaneous Disorders with Amlexanox.

#### ARTICLE 2 -- GRANT

2.1 Grant: Block hereby grants Access the exclusive right under the Licensed Patents and the Block Know-How to make, use, have made and sell or have sold any Product within the Territory during the Term, including the right to make or have made outside the Territory for sale in Territory. The rights granted hereunder, however, are subject to the rights granted to Block Takeda as set forth in the Takeda License Agreement and the Takeda Supply Agreement. Access agrees to be bound by the royalty provisions in such agreements, as amended from time to time.

# ARTICLE 3 -- ACCESS ROYALTIES/MILESTONE PAYMENTS

#### 3.1 Milestone Payments:

In consideration of the license of the Product by Block, Access shall make certain non-refundable milestone payments to Block as enumerated in paragraph 3.2 below and Royalty payments as set forth in paragraph 3.3 below. Each of the payments is subject to the terms and conditions herein contained, including, without limitation either parties right to terminate this Agreement under Article 6.

3.2 Payment Schedule: Subject to paragraph 3.1 above, Access shall make the following payments to Block in the form and manner described below:

(a) Upon execution of this Agreement and receipt of Takeda's consent to this Agreement pursuant to Article 9 hereof, Access shall pay Block the sum of \*;

\* - Confidential portions have been omitted and are on file separately with the Commission.

#### 8

(b) Subject to receipt of Takeda's consent to this Agreement pursuant to Article 9, \* from the date of execution of this Agreement, Access shall pay Block the sum \*;

(c) Subject to receipt of Takeda's consent to this Agreement pursuant to Article 9, \* from the date of execution of this Agreement, Access shall pay Block the sum of \*;

(d) Within five (5) business days after Access signs a license agreement or agreements regarding Product for all the major European markets of Germany, France, the United Kingdom, Italy and Spain, Access shall pay

Block the sum of \*;

(e) Within five (5) business days after Access signs a license agreement regarding Product for the United States market, Access shall pay Block the sum of \*;

(f) Within five (5) business days of the filing by Access of a New Drug Application ("NDA") for Product with the U.S. Food and Drug Administration, Access shall pay Block the sum of \*;

(g) Within five (5) business days of Access receiving a written approval of an NDA

\* - Confidential portions have been omitted and are on file separately with the Commission.

for Product, Access shall pay to Block the sum of \* .

9

For the avoidance of doubt, only one payment is required under each of the subsections of this paragraph, notwithstanding whether more than one Product is developed or more than one NDA is filed for a Oral Mucositis Use/Mucositis Indication and whether or not there are any improvements.

3.3 Royalty Payments: As further consideration of the license of the product by Block to Access, Access shall pay to Block the following royalties based upon the following Cumulative Worldwide Net Sales milestones:

PAYMENT MILESTONE

\* On achievement of Cumulative Worldwide Net Sales revenue of \$5,000,000

\* On achievement of Cumulative Worldwide Net Sales revenue of \$15,000,000

\* On achievement of Cumulative Worldwide Net Sales revenue of \$30,000,000

 $\ast$  - Confidential portions have been omitted and are on file separately with the Commission

10

\* On achievement of Cumulative Worldwide Net Sales revenue of \$50,000,000

\* On achievement of Cumulative Worldwide Net Sales revenue of \$75,000,000

\* On achievement of Cumulative Worldwide Net Sales revenue of \$100,000,000

3.4 Ouarterly Royalty Reports: Actual payment of the royalties described in 3.2, above, will be based upon quarterly reports by Access to Block. Within thirty (30) days of the end of each Calendar Quarter, commencing with the first full calendar quarter following the Effective Date of this Agreement, Access shall submit to Block a written report setting forth the Cumulative Worldwide Net Sales for such quarter provided, however, that the first such quarterly report shall include Cumulative Worldwide Net Sales from the Effective Date of this Agreement to the end the first full Calendar Quarter. In the event that Access sublicenses the Product to a third pa hereunder, Access shall require said third Party to submit to Access a written report of the parties Sublicensee Net Sales each quarter. A copy of any such sublicensee report shall be included in the Access report for the relevant quarter. When in any Ouarterly Report from Access and/or any third party sublicensee, one of the Cumulative Worldwide Net Sales milestones set forth in paragraph 3.2, above, as indicated have been achieved, Access shall make the corresponding royalty

\* - Confidential portions have been omitted and are on file separately with the Commission.

payment to Block within forty-five (45) business days after the end of the Quarter in which the milestone is achieved.

3.5 Payment of Royalties: All royalty payments described in paragraphs 3.1 and 3.2, above, shall be made at Block's discretion by wire transfer or certified check.

#### ARTICLE 4 -- ADDITIONAL OBLIGATIONS OF THE PARTIES

4.1 Access to Pay Registration Fees and Costs: Access or its sublicensees shall pay all registration fees, clinical evaluation costs and any other costs associated with obtaining approval to market any Product within any country in the Territory.

4.2 Access to Pay Takeda Royalties to Block: Access shall pay all royalties due under the Takeda agreement for sales of Products within the Territory directly to Block, and Block shall be solely responsible for remitting all such payments due to Takeda for sales of Product within the Territory under the terms of the Takeda License Agreement. Block shall notify Access in writing of all royalties actually due to Takeda and shall provide written evidence to Access of its remittance of such payment to Takeda.

4.3 Access to Provide Data: Access shall supply Block on a quarterly basis, without compensation, with all clinical and other technical and scientific data that it develops relating to any Product. Block may use this data at its discretion for any purpose, including, but not limited to,

12

filing of such data with regulatory authorities outside the Territory for any purpose. Information pertaining to side effects resulting from any use of Amlexanox in any type of application will be exchanged by both parties hereto on an emergent basis, whenever such information is obtained.

# ARTICLE 5 -- BLOCK IMPROVEMENT RIGHTS AND OBLIGATIONS

# 5.1 Grant of Rights to Block: Access hereby grants Block the exclusive right of first refusal

to license Oral Mucositis Use/Mucositis Indication Improvements, if any, and Access Know-How if any, now existing or subsequently developed, to make, use, have made and sell any Oral Mucositis Use/Mucositis Indication Improvements outside the Territory during the Term, including, but not limited to, the right to make or have made the Oral Mucositis Use/Mucositis Indication Improvements, or any part thereof, within the Territory for sale outside the Territory. Block shall have the right to sublicense the rights granted hereunder outside the Territory at its sole discretion.

#### ARTICLE 6 -- TERM AND TERMINATION

6.1 Term: The Term of this Agreement for any Product commences on the Effective Date hereof and ends, on a country by country basis upon the later of twenty (20) years from the date of First Sale of a Product in such country or the expiration, lapse, termination or unappealed or unappealable determination of invalidity, unenforceability or nonallowability of the last Licensed Patent in each country, if any. The Term for Improvements shall commence on the Effective Date and shall end, on a country-by-country basis, upon the later of twenty (20) years from the date of

#### 13

First Sale of an Improvement in such country or the expiration, lapse, termination or unappealed unappealable determination of invalidity, unenforceability or nonallowability of the last Licensed Patent, if any, or Improvement Patent, if any, in each country. In no event, however, shall the duty to pay royalties under this Agreement extend beyond twenty (20) years after the Effective Date. Royalties payable to Takeda under the Takeda License Agreement shall not be affected by any provision of this Paragraph.

At the conclusion of the Term, each party shall have a fully paid-up worldwide nonexclusive license with respect to any Licensed Patent, Improvement Patent, Block Know-How and Access Know-How, and no further payments shall be made or required under this Agreement. 6.2 Termination for Breach: Either party may terminate this Agreement on sixty (60) days'

written Notice to the other if the other is in default or breach of any material provision, provided however, that if the party receiving such Notice cures or diligently commences to cure the breach or default within such sixty (60) day period, this Agreement shall continue in full force and effect. If such default or breach of a material provision is a failure to pay any amount due and owing hereunder, the terminating party may terminate this Agreement on thirty (30) days' written Notice. If, however, the party receiving such Notice cures such default or breach within such thirty (30) day period, this Agreement shall continue in full force and effect. Failure to terminate this Agreement for any default or breach shall not constitute a waiver by the aggrieved party of its right to terminate the Agreement for any other default or breach.

#### 14

6.3 Rights to Survive: Termination shall not affect the rights of the parties accruing up the effective date of termination and thereafter as to provisions which expressly survive termination

6.4 Reversion and Termination for Failure to Pay Takeda License Fees: If Access fails to make any payment to Block under Paragraph 4.2, then all rights granted to Access in this Agreement shall revert to Block thirty (30) days after Notice to Access from Block of such failure to pay. If Access makes all payments to Block required under Paragraph 4.2 and any other required payments hereunder as set forth in such Notice within the thirty (30) days, then such rights shall not revert Block.

6.5 Termination of Takeda Supply Agreement or Takeda License Agreement: Block shall use its best commercially-reasonable efforts to keep the Takeda Supply Agreement and Takeda License Agreement in effect during the Term of this Agreement, and further in the event the Take Supply Agreement or Takeda License Agreement is terminated by reason of breach by Block, Block shall give Access Notice at least thirty (30) days prior to any such termination, and Access shall have the right to cure any breach that is the cause of any termination. In addition, should the Takeda Supply Agreement be terminated or canceled by Takeda, Block shall use its best commercially reasonable efforts to secure an alternative source of supply for Amlexanox. In no event, however will Block have any obligation to manufacture Amlexanox nor give up its own supplies of Amlexanox in order to supply Access. Should the Takeda License Agreement be terminated or canceled by Takeda, any obligation of Block' s in this Agreement which is thereby rendered non-

#### 15

performable shall be deemed severed from this Agreement without penalty to Block but the remainder of this Agreement shall remain in full force and effect.

# **ARTICLE 7 -- WARRANTIES**

7.1 Exploitation of licensed Rights: Block makes no warranty or representation that the use

of any Products, the practice of the Licensed Patents, or the use of any trademark will result in the successful promotion, marketing or sale of the Products. Access makes no warranty or representation that the use of any Improvements, the practice of the Improvements, or the use of any trademark will result in the successful promotion, marketing or sale of the Improvements.

7.2 Access Indemnity: Access shall indemnify and hold Block harmless against any and all liability, damage, loss, cost or expense (including reasonable attorneys' fees and expenses), hereinafter "Damages," resulting from any third party claim made or suit brought against Block to the extent that such claim or suit (i) is caused by Access' negligence or willful misconduct; (ii) is caused by Access' breach of any of the representations or warranties set forth herein; or (iii) is caused by Access' breach of this Agreement. As the parties intend full indemnification, all costs, expenses and fees, including reasonable attorneys' fees and disbursements, incurred in enforcing this Paragraph 7.2 shall also be reimbursed. Upon filing of any such claim or suit, Block shall immediately Notify Access thereof and shall permit Access at its cost to handle and control such claim or suit. Block shall have the right to participate in the defense of such claim or suit at its

#### own expense.

#### 16

7.3 Block Indemnity: Block shall indemnify and hold Access harmless against any and liability, damage, loss, cost or expense (including reasonable attorneys' fees and expenses), hereinafter "Damages," resulting from any third party claim made or suit brought against Access the extent that such claim or suit (i) is caused by Block's negligence or willful misconduct; (ii) is caused by Block's breach of any of the representations and warranties set forth herein; or (iii) is caused by Block's breach of this Agreement. As the parties intend full indemnification, all costs, expenses and fees, including reasonable attorneys' fees and disbursements, incurred in enforcing this Paragraph 7.3 shall also be reimbursed. Upon filing of any such claim or suit, Access shall immediately Notify Block thereof and shall permit Block at its cost to handle and control such claim or suit at its own expense.

7.4 Obligations Regarding. Patent Infringement: In the event of alleged infringement of one or more patents licensed hereunder by a third party:

(a) each party shall Notify the other of any perceived or threatened infringement of the Takeda patents by any third party as such party becomes aware of such perceived or threatened infringement. Block shall Notify Takeda of any such perceived or threatened infringement, and all actions with respect to the Takeda Sublicensed Patents will be governed by Paragraph 9.1 of the Takeda Agreement;

(b) In the event of infringement of any patent owned or licensed by Block and

#### 17

licensed under this Agreement, the party discovering the infringement shall Notify the other party of such infringement. Block shall have sixty (60) days from the date of such Notice to Notify Access of its decision to enforce or not to enforce the patent. If Block elects not to enforce such patent within such sixty (60) day period, then Access may, at its option, enforce such patent. In the event of any legal action seeking to enforce any patent owned by Block, both Access and Block may be named as party plaintiff. No settlement, consent judgment or other voluntary final disposition of such suit may be entered into by Access without the consent of Block, which consent shall not be unreasonably withheld or delayed.

(c) In the event of any lawsuit against a third party hereunder, the parties agree cooperate to with each other in all respects relating to the lawsuit. Either party or both parties may actively assert a patent. Damages or any amount received in settlement of claims of infringement shall be apportioned as follows: (1) the party that actively asserted the patent or patents found to be infringed or were covered by any settlement of claims shall first be reimbursed for one hundred and twenty five percent (125%) of its out-of-pocket expenses, including reasonable attorneys' fees, expended in actively asserting such patent or patents; (2) out of the remainder, the party that did not actively assert such patent or patents shall be reimbursed for one hundred and twenty five percent (125%) of its outof-pocket expenses, including reasonable attorneys' fees, expended in such lawsuit; and (3) the party that actively asserted such patent or patents shall then receive any remaining funds from such damage award or settlement. If both parties actively asserted such patent or patents, then the parties will divide funds from such damage award or settlement as follows: each party shall receive one hundred and twenty five percent (125%) of its out-ofpocket expenses, including

#### 18

reasonable attorneys' fees, expended in such lawsuit and the parties shall share any remaining funds in a ratio to the profit the party is deriving from the sale of the Product. If the funds from such damage award or settlement are not sufficient to compensate both parties for one hundred and twenty five percent (125%) of their expenses, then the funds shall be divided in a ratio equal to the ratio of the out-of-pocket expenses, including reasonable attorneys' fees, of each party.

7.5 Claims by Third Parties: In the event a party to this Agreement is sued or threatened with suit by a third party and such action pertains to the

Products, the party being threatened shall give prompt Notice to the other party. The parties agree to confer together in such event and consult with one another with respect to the action to be taken.

7.6 No Restrictions on Product: Each party represents to the other that it has no knowledge of violations of any law or regulation or restrictions on the ability to make, use or sell the Product, other than ordinary restrictions imposed in countries in which governmental approval is required but has not yet been obtained, to market in such countries and other than restrictions imposed by the Takeda License Agreement and the Takeda Supply Agreement.

7.7 Power to Enter Into Agreement: Each party represents that it has no knowledge of any

impediment to it entering into this Agreement except for the required consent by Takeda to the Agreement.

7.8 No Other Warranties or Representations: Nothing in this Agreement shall be construed

#### 19

as (a) a warranty or representation by Block or Access as to the validity or scope of any patent; (b) a warranty or representation that anything made, used, sold, or otherwise disposed of under any license granted in this agreement is or will be free from infringement of patents of third parties; (c) an obligation to bring or prosecute actions or suits against third parties for infringement; or (d) conferring a right to use in advertising, publicity or otherwise any trademark or trade name of Block or Access.

7.9 Warranties of Block: Neither party makes any representation, extends any warranties of any kind, either: express or implied, or assumes any responsibilities whatever with respect to use, sale, or other disposition by any party of any Product or Improvement, with the exception that Block hereby warrants as follows:

(a) Block is the owner of the entire right, title and interest in and to the Block Patent(s).

(b) Block has not assigned or licensed the rights to the Block Patent(s) to any other party.

(c) Block has the full power and authority to enter into this Agreement and grant the exclusive licenses granted hereunder.

# 20 ARTICLE 8 -- MISCELLANEOUS

8.1 New Jersey Law Applies: This Agreement shall be interpreted and construed in accordance with the laws of the State of New Jersey.

8.2 Alternative Dispute Resolution: All disputes relating to or arising out of this Agreement

or its subject matter shall be resolved by the parties as set forth in this Paragraph 8.2.

(a) In the event of a dispute, Notice of a demand for a meeting of the parties to discussed and settle a dispute ("Notice of Meeting") may be given by either party. Such Notice shall be in writing and shall set a date no more than ten (10) business days from the date of the Notice of Meeting on which the parties shall meet during normal business hours at a mutually acceptable place. If within five (5) days after the date of the meeting the parties have not resolved their dispute(s), then the parties shall proceed as provided below. Notwithstanding anything in this Paragraph 10.2 to the contrary, either party may seek equitable and injunctive relief in any state or federal court in which jurisdiction and venue are proper.

(b) Any dispute not resolved within five (5) days after the meeting shall be resolved by means of alternative dispute resolution, as provided in the New Jersey Alternative Procedure for Dispute Resolution Act, N.J.S.A. 2A:23A-1 et seq. (the "Act"). Other than as set forth herein to the contrary, the parties expressly waive the right to resolve all claims, disputes and issues arising out of or relating to this Agreement by means of traditional litigation, including the right to appeal,

except as provided in the Act. Except as otherwise provided in this Agreement, the Act shall govern the procedures and methods for any ADR Proceeding. No punitive damages may be awarded in any litigation or ADR Proceeding.

(c) Notice of a demand for resolution of a dispute under the Act (a "Notice of Dispute") given by either party shall be in writing specifying the issue or issues in dispute.

(d) Within fifteen (15) days after a Notice of Dispute is given, each party shall select two (2) prospective umpires from among (i) any retired judge of the federal courts or state appellate courts of New Jersey or New York; (ii) any retired managing partner of a law firm with no less than twenty-five (25) partners; or (iii) such other person with such qualifications upon which the parties agree. The umpires shall be free from bias and conflict of interest with respect to either party and shall be in a position to immediately hear the dispute and render a prompt resolution, but in no event later than six (6) months from the date of the Notice of Dispute. Within fifteen (15) days after each party has selected its prospective umpires, the parties shall agree to one (1) umpire from among the four (4) prospective umpires to hear the dispute. In the event that the parties do not agree on an umpire, the prospective umpires shall name the umpire.

The proceeding for the alternative resolution of a dispute (the "ADR Proceeding") shall be held at a location with in the State of New Jersey or New York as selected by the umpire and shall commence no later than forty (40) days after the Notice of Dispute is given.

#### 22

The fees payable to the umpire shall be the usual hourly rate of such umpire for consulting or dispute resolution services. All fees and expenses associated with the ADR Proceeding incurred by the parties, including the umpire fees, reasonable attorneys' fees and disbursements, shall be paid by the party against whom the decision is rendered.

8.3 No Agency or Employment: Neither Block nor Access is to be considered the agent or employee of the other for any purpose, and neither party has the right or authority to enter into any contracts or assume obligations for the other or to give any warranty or make any representation on behalf of the other party except where and to the extent specifically authorized in writing to do so.

8.4 Notice: Every notice or other communication required or contemplated by this Agreement by either party shall be in writing.

(a) Every notice or other communication required or contemplated by this Agreement by either party shall be delivered to the other party by either: personal delivery; or facsimile; or certified or registered mail, postage prepaid, addressed to the party for whom such notice was intended; or by overnight courier.

(b) Notice delivered in person shall be deemed to have been delivered upon receipt by the party to whom such notice was sent.

#### 23

(c) Notice delivered by facsimile shall be deemed to have been delivered at noon on the first business day after the date on which the facsimile was sent.

(d) Notice by certified mail shall be deemed to have been delivered on the date it is officially recorded as delivered to the intended recipient by return receipt or equivalent, and in the absence of such record of delivery, the effective date shall be presumed to have been the fifth (5th) business day after it was deposited in the mail.

(e) Notice delivered by overnight courier shall be deemed to have been delivered upon receipt by the party to whom such notice was sent.

(f) Unless Access receives notice to the contrary, all notices directed to Block shall be sent to the attention of:

John E. Peters, Esq. Senior Vice President and General Counsel Block Drug Company, Inc. 257 Cornelison Avenue Jersey City, New Jersey 07302 Fax: (201) 333-35 85

(g) Unless Block receives notice to the contrary, all notices directed to Access shall be sent to the attention of:

24 Kerry P. Gray President and Chief Executive Officer Access Pharmaceuticals, Inc. 2600 Stemmons Freeway, Suite 176 Dallas, Texas 75207 Fax: (214) 905-5101

with a copy to:

Bingham Dana LLP 150 Federal Street Boston, MA 02110-1726 Attn: John J. Concannon Telephone: (617)951-8874 Fax: (617)951-8736

8.5 Severability: Whenever possible, each section, subsection, provision or condition of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any section, subsection, provision or condition of this Agreement should be prohibited or invalid under applicable law, such section, subsection, provision or condition shall be considered separate and severable from this Agreement to the extent of such prohibition or invalidity without invalidating the remaining sections, subsections, provisions and conditions of this Agreement.

8.6 Entire Agreement/Merger: This Agreement sets forth the entire agreement between the parties hereto pertaining to the subject matter hereof and supersedes all negotiations, preliminary agreements, memoranda or letters of proposal or intent, discussions and understandings of the parties hereto in connection with the subject matter hereof. All discussions between the parties have been merged into this Agreement, and neither party shall be bound by any definition, condition,

#### 25

understanding, representation, warranty, covenant or provision other than as expressly stated in or contemplated by this Agreement or as subsequently shall be set forth in writing and executed by a duly authorized representative of the party to be bound thereby.

8.7 Amendment: No amendment, change or modification of any of the terms, provisions or conditions of this Agreement shall be effective unless made in writing and signed on behalf of the parties hereto by their duly authorized representatives.

8.8 Counterparts: This Agreement may be executed in one or more counterparts, each which shall be deemed to be an original document, but all such separate counterparts shall constitute only one and the same instrument.

8.9 No Waiver of Rights: No waiver of any term, provision, or condition of this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision, or condition of this Agreement.

8.10 Force Majeure: Neither party shall be liable hereunder to the other party nor shall be in breach for failure to deliver, provided failure to deliver is no greater than the delay in time caused by circumstances beyond control for either party, including but not limited to acts of God, fires, floods, riots, wars, civil disturbances, sabotage, accidents, labor disputes, shortages, government actions (including but not limited to priorities,

requisitions, allocations and price adjustment restrictions) and inability to obtain material, equipment, labor or transportation.

26

8.11 Further Assurances: The parties hereto shall each perform such acts, execute and deliver such instruments and documents and do all such other things as may be reasonably necessary to accomplish the transactions contemplated in this Agreement.

8.12 Audit Rights: Each party shall keep books and records in sufficient detail to permit the other to verify items relating to this agreement including, but not limited to, Access Cumulative Worldwide Net Sales and Takeda Royalties paid by Block. Each party shall have the right, upon reasonable Notice and during normal business hours, but in no event more frequently than once during any twelve (12) month period or more than two (2) years after the close of any party's fiscal year, to audit, or have audited by a Certified Public Accountant, the relevant books and accounts to verify the accuracy of the reported Cumulative Worldwide Net Sales. In the event such audit reveals that the audited party has mis-reported information by more than two percent (2%), that party, in addition to paying or reimbursing any additional amounts due, shall pay the reasonable costs associated with such audit. The parties shall maintain the results of any such audit in confidence. All records pertaining to any payment shall be maintained for not less than five (5) years after the year of payment hereunder.

8.13 Binding Effect: This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective permitted successors and assigns.

8.14 No Strict Construction: This Agreement has been prepared jointly and shall not be strictly construed against either party.

# 27

8.15 Consent Not Unreasonably Withheld or Delayed: Whenever provision is made in this Agreement for either party to secure the consent or approval of the other, such consent or approval shall not unreasonably be withheld or delayed, and whenever in this Agreement provisions made for one party to object to or disapprove a matter, such objection or disapproval shall not unreasonably be exercised.

8.16 Bankruptcy: At least thirty (30) days prior to filing a petition in bankruptcy, each party must inform the other of its intention to file the petition or of a third party's written Notice of its intention to file a voluntary or an involuntary petition in bankruptcy.

8.17 Assignment: Block may assign this Agreement to any parent, affiliate, subsidiary or entity in common control without the consent of Access. Block may also assign this agreement to a third party, either alone or as part of an agreement to dispose of all or a substantial part of its assets or business. In the event of an assignment, the assignee shall have the identical rights granted to Block hereunder. Block may assign this agreement to a third party as part of an agreement to dispose of a substantial part of its business without the consent of Access. If Block wishes to assign this agreement alone to a third party, however, such assignment shall not take place without Access' written consent. If Access wishes to assign this agreement, such assignment shall not take place without the written consent of Block and Takeda which shall not be unreasonably withheld.

8.18 Taxes: All taxes levied on account of royalties accruing under this Agreement shall be paid by the receiving party. If laws or regulations require withholding of taxes, the taxes will be

# 28

deducted by the paying party from remittable royalty payments and will be paid by the paying party to the proper taxing authority. Proof of payment shall be sent to the receiving party within sixty (60) days following payment.

8.19 Cooperation on Publicity: Access and Block shall not, except as required by law and in interviews between professional sales representatives and a potential prescribers of a Product or Improvement, use each other's name in any manner, or issue any public statement disclosing the existence of, or relating to, this Agreement or any of the activities conducted hereunder, without the other party's prior written permission. To the extent this Agreement triggers, in the opinion of counsel, an obligation for a party to file a report with the SEC on Form 8-K or any other form, such party shall either (1) not file a copy of this Agreement or (2) request SEC approval for the deletion of certain confidential information identified jointly by parties and then file a redacted version of this Agreement. Access shall not publish, or allow to be published, any manuscript, article, report of other form of oral or written presentation regarding Amlexanox without the express written approval of Block.

8.20 Costs of Agreement: The parties hereto shall each bear their own costs and expenses (including reasonable attorneys' fees) incurred in connection with the negotiation and preparation of this Agreement and consummation of the transactions contemplated hereby.

8.21 Headings For Convenience Only: The titles, headings or captions and paragraphs in

this Agreement do not define, limit, extend, explain or describe the scope or extent of this

#### 29

Agreement or any of its terms or conditions and therefore shall not be considered in interpretation, construction or application of this Agreement.

8.22 Independent Contractor: Each party is an independent contractor with respect to the other, and is not an agent, partner, joint venturer, or employer of the other. Neither party shall have any responsibility for the hiring, termination, compensation or benefits of the other party's employees. No employees or representatives of either party shall have any authority to bind or obligate the other party for any sum or in any manner whatsoever, or to create or impose any contractual or other liability on the other party without said party's authorized written approval.

8.23 No Finder's Fee: The parties acknowledge that no "finder" has been involved in bringing the parties together and that no compensation is due to any third party(s) as a result of the execution of this Agreement.

8.24 Notification of Infringement: Each party shall promptly Notify the other party of any infringement or misappropriation based upon or arising from any of the intellectual property that is the subject of this agreement.

8.25 References: All references herein to articles, sections, paragraphs and attachments shall be to articles, sections, paragraphs and attachments of this Agreement.

#### 30

8.26 Singular and Plural: The use herein of the singular form shall also denote the plural form, and the use herein of the plural form shall denote the singular form as in each case the context may require.

8.27 Successors and Assigns: This Agreement shall be binding upon and shall inure the benefit of the parties hereto and their respective successors and assigns permitted under this Agreement.

8.28 Validity and Severability: Whenever possible, each clause, subclause, provision or condition of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law, but if any clause, subclause, provision or condition of this Agreement should be prohibited or invalid under applicable law, such clause, subclause, provision or condition shall be considered separate and severable from this Agreement to the extent of such prohibition or invalidity without invalidating the remaining clauses, subclauses, provisions and conditions of this Agreement.

8.29 Waiver: No waiver of any term, provision, or condition of this Agreement, whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision, or condition of this Agreement.

8.30 Takeda Agreements Controlling: This Agreement is subject to the Takeda License Agreement and the Takeda Supply Agreement. To the extent that any term of this Agreement is inconsistent with either the

Takeda License Agreement or the Takeda Supply Agreement, such term

31

shall be controlled by and subject to the terms of the Takeda License Agreement and the Takeda Supply Agreement.

ARTICLE 9 -- TAKEDA APPROVAL AND SUPPLY OF RAW MATERIAL

9.1 Takeda Approval: This Agreement shall be binding on the parties but not become effective until receipt by Block of written approval from Takeda for Block to enter into this Agreement. If Takeda disapproves this Agreement or fails to approve the Agreement within six (6) months of the Effective Date, then this Agreement shall be void in its entirety. Block shall use best efforts to obtain Takeda's consent to this Agreement.

9.2 Takeda Supply of Raw Material: In the event that Takeda, during the term of Agreement, ceases to produce and/or supply Amlexanox, the active ingredient for the product, to Block, Block agrees to cooperate with Access in using reasonable efforts to locate a new source of supply but in no event will Block be liable to Access for damages of any kind caused by the cessation of production and/or supply of Amlexanox by Takeda, nor in that event, will Block required to provide any of its supply of Amlexanox designated for Block's product needs to meet the needs of Access. Block agrees to use best efforts to enforce the provisions of the Takeda Supply Agreement.

32

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duty executed as of the day and year first above written.

ACCESS PHARMACEUTICALS, INC. BLOCK DRUG COMPANY, INC. By: /s/ Kerry P. Gray By: /s/ Arthur J. Looney

5 5 5	5
Kerry P. Gray	Arthur J. Looney
Name Printed	Name Printed
President and CEO	Vice-President/General Manager
Title	Title
December 18, 1998	December 21, 1998

33

# EXHIBIT 21

# Subsidiaries of the Registrant

Tacora Corporation, a Delaware company

Access Holdings, Inc., a Delaware company

# EXHIBIT 23.1

# Consent of Independent Certified Public Accountants

The Board of Directors and Stockholders Access Pharmaceuticals, Inc.

We consent to the incorporation by reference in Registration Statement Nos. 33-10626 and 33-41134 on Form S-8 of our report dated February 12, 1999, relating to the 1998 consolidated financial statements of Access Pharmaceuticals, Inc. and subsidiary, which report appears in the December 31, 1998 Annual Report on Form 10-K of Access Pharmaceuticals, Inc.

Our report dated February 12, 1999, contains an explanatory paragraph that states that there is substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ Grant Thornton LLP

- -----Grant Thornton LLP

Dallas, Texas March 26, 1999

# EXHIBIT 23.2

#### Consent of Independent Certified Public Accountants

The Board of Directors and Stockholders of Access Pharmaceuticals, Inc.

We consent to the incorporation by reference in Registration Statement Nos. 33-10626 and 33-41134 on Form S-8 of Access Pharmaceuticals, Inc. (formerly Chemex Pharmaceuticals, Inc.) of our report dated March 24, 1998, relating to the consolidated balance sheet of Access Pharmaceuticals, Inc. and subsidiary (a development stage company) as of December 31, 1997 and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the two-year period ended December 31, 1997 and for the period February 24, 1988 (inception) to December 31, 1997, which report appears in the December 31, 1998 Annual Report on Form 10-K of Access Pharmaceuticals, Inc. The cumulative statements of operations, stockholders' equity (deficit), and cash flows for the period February 24, 1988 (inception) to December 31, 1988 and for each of the years in the six-year period ending December 31, 1994, which were audited by other auditors whose report has been furnished to us and is included herein, and our opionion, insofar as it relates to the amounts included for the period February 24, 1988 (inception) through December 31, 1994, is based solely on the report of the other auditors.

Our report dated March 24, 1998, contains an explanatory paragraph that states that the Company has suffered recurring losses from operations and has a net capital deficiency, which raise substantial doubt about its ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty.

/s/ KPMG LLP

- -----KPMG LLP

Dallas, Texas March 26, 1999

# EXHIBIT 23.3

Independent Auditors' Consent

The Board of Directors and Stockholders of Access Pharmaceuticals, Inc.

We consent to the incorporation by reference in Registration Statement Nos. 33-10626 and 33-41134 on Form S-8 of our report dated September 21, 1995, relating to statements of operations, stockholders' equity and cash flows for the period February 24, 1988 (inception) through December 31, 1994 which report appears in the December 31, 1998 annual report on Form 10-K of Access Pharmaceuticals, Inc.

/s/ Smith Anglin & Co.

Smith Anglin & Co.

Dallas, Texas March 26, 1999 <ARTICLE> 5 <LEGEND> THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION FROM THE CONSOLIDATED BALANCE SHEET AND THE CONSOLIDATES STATEMENT OF OPERATIONS AS A PART OF THE ANNUAL REPORT ON FORM-10K AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH ANNUAL REPORT ON FORM 10-K. </LEGEND> <MULTIPLIER> 1,000 <S> <C> <PERIOD-TYPE> 12-MOS <FISCAL-YEAR-END> DEC-31-1998 <PERIOD-START> JAN-01-1998 <PERIOD-END> DEC-31-1998 1,487 <CASH> <SECURITIES> 0 <RECEIVABLES> 0 <ALLOWANCES> 0 <INVENTORY> 0 <CURRENT-ASSETS> 1,541 <PP&E> 1,007 <DEPRECIATION> 780 <TOTAL-ASSETS> 2,351 <CURRENT-LIABILITIES> 532 <BONDS> 0 <PREFERRED-MANDATORY> 0 <PREFERRED> 0 34 <COMMON> <OTHER-SE> 1,761 <TOTAL-LIABILITY-AND-EQUITY> 2,351 <SALES> 0 <TOTAL-REVENUES> 0 <CGS> 0 <TOTAL-COSTS> 3,433 <OTHER-EXPENSES> 0 <LOSS-PROVISION> 0 <INTEREST-EXPENSE> 22 <INCOME-PRETAX> (3,397) <INCOME-TAX> 0 (3,397) <INCOME-CONTINUING> <DISCONTINUED> 0 <EXTRAORDINARY> 0 0 <CHANGES> (3, 397)<NET-INCOME> <EPS-PRIMARY> (1.28)<EPS-DILUTED> (1.28)

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