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## 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, 1995

Commission File Number 0-9314

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

Delaware 82-0221517

(State of Incorporation) (I.R.S. Employer I.D. No.)

2600 Stemmons Freeway, Suite 210, Dallas, TX 75207

(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number, Including Area code: (214) 905-5100

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

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

Common Stock, Four Cents (\$0.04) 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 requirement for the past 90 days. Yes [check mark] 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 registrants knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K. []

The aggregate market value of the outstanding voting stock held by non-affiliates of the registrant as of February 29, 1996 was approximately \$22,000,000.

As of February 29, 1996 there were 22,718,767 shares of ACCESS Pharmaceuticals, Inc. common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: None

## PART I - FINANCIAL INFORMATION

#### ITEM 1. DESCRIPTION OF BUSINESS

Operations Prior to January 1996

ACCESS 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 name of the Company was changed to ACCESS Pharmaceuticals, Inc.

ACCESS' principal executive office is at 2600 North Stemmons Freeway, Suite 210, Dallas, Texas 75207; its telephone number is (214) 905-5100.

In June 1990, ACCESS sold its then lead drug, Actinex(TM), a drug developed by ACCESS for the treatment of actinic keratoses (pre-malignant lesions of the skin) to Block Drug Company ("Block") for a total of \$8 million in milestone payments plus future royalties which to date have not been significant. As of December 31, 1992, all milestones were achieved and paid, and Block began selling the drug in November 1992. ACCESS has retained the right to the active ingredient of Actinex(TM) for all applications other than the indications for premalignant lesions of the skin and basal cell carcinoma.

In June 1991, ACCESS entered into a joint venture agreement with Block for the development, manufacturing and marketing of certain dermatological products (the "Joint Venture"). Under this Joint Venture, Amlexanox, a drug for canker sores,

was developed.

Following the dissolution of the Joint Venture as of December 31, 1994, ACCESS jointly owned the rights to Amlexanox with Block. ACCESS was required to share certain research and development and other expenses relating to the commercialization of Amlexanox on a 50/50 basis with Block. These agreements also provided that if ACCESS was unable to fund its shares of such expenses, ACCESS would be entitled to receive royalties from future sales of Amlexanox.

Believing that it would not be able to continue to fund its share of the expenses required for commercialization of Amlexanox and because it was unable to (a) raise additional equity financing and (b) reach agreement, by letter of intent or otherwise, on a merger transaction with a third party, ACCESS, on May 30, 1995, exercised an option to sell its rights to Amlexanox to Block. On September 14, 1995, at a Special Meeting of Stockholders, the ACCESS Stockholders approved such sale and such transaction was consummated on September 21, 1995.

As consideration for the sale of ACCESS' share of Amlexanox, Block (a) made a nonrefundable upfront royalty payment of \$2.5 million; (b) is obligated to pay to ACCESS \$1.5 million as a prepaid royalty at the end of the calendar month during which Block together with any sublicensee has achieved cumulative worldwide sales of Amlexanox oral products of \$25 million; and (c) after the payment of such \$1.5 million royalty, is obligated to pay to ACCESS for all sales in excess of cumulative worldwide sales of Amlexanox oral products of \$45 million:

(1) for all countries where a valid and enforceable patent of Takeda Chemical Industries, Ltd., ("Takeda"), the licensor of Amlexanox to Block, and or/an Amlexanox patent for canker sores is in effect at the time of sale:

Ethical formulations: 5% Over the Counter ("OTC") formulations: 2.5%

(2) for countries where there is no valid and enforceable Takeda patent or Amlexanox patent for canker sores in effect at the time of a sale:

Ethical formulations: 2.5% OTC formulations: 1.25%

ACCESS' obligations following such sale are limited to performing reasonable activities in support of obtaining FDA approval of Amlexanox until the earlier of (i) three years after FDA approval of Amlexanox, or (ii) the liquidation or dissolution of ACCESS. An NDA for Amlexanox was filed in April 1995 and the Company is awaiting approval of this product. As a result, there have been no sales of Amlexanox to date.

Until July 1995 and the sale of the drug Amlexanox to Block, ACCESS focused on the development of novel drugs for the treatment of various skin diseases and had a diversified portfolio of drugs under development.

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 through the utilization of its patented and proprietary endothelial binding technology which selectively targets sites of disease.

This new technology was researched and developed at the University of Texas Southwestern Medical Center by Dr. David Ranney, API's founder, who was the Director of the Laboratory of Targeted Diagnosis and Therapy in the departments of Pathology and Radiology. The technology is being developed to increase the efficacy and reduce the side effects of therapeutics and diagnostic agents by selectively targeting them to the sites of disease and accelerating drug clearance. The principal form of the technology utilizes natural carbohydrates, glycosaminoglycans ("GLYCOS"), as the carrier system which selectively targets sites of disease. GLYCOS work by recognizing and adhering to cytokine-induced adhesive receptors on the walls of local blood vessels.

The therapeutic focus of ACCESS is the development of proprietary pharmaceuticals for the treatment of cancer and life-threatening infections and the diagnosis and staging of cancer. ACCESS believes that the unique pharmacologic profiles and selective targeting properties of GLYCOS could allow its product candidates to become useful treatments for cancer and life-threatening infections, and important diagnostic tools in the early detection, prognosis and monitoring of cancer. The focus on acute care in large expanding high-value hospital markets, particularly in the areas of oncology and infectious disease, is designed to more rapidly accelerate development and regulatory review and lower development cost in these life saving therapeutic areas.

ACCESS has developed four possible product candidates, two of which are believed ready to be advanced into human testing. These product candidates are new formulations of existing compounds which increase therapeutic efficacy and reduce toxicity, designed to address the clinical shortfalls of available treatments.

The ACCESS strategy is to initially focus on utilizing its GLYCOS technology in combination with approved drug substances to develop novel patentable physical formulations of potential therapeutic and diagnostic products. It is anticipated 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 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 physical 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. The

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manufacturing scale-up, pre-clinical 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. Potential strategic partners are and will continue to be screened based on the technology synergy, development capabilities, expertise in the therapeutic/diagnostic area and ability to globally maximize the potential product opportunity. Strategic alliance agreements are expected to be structured around milestone and diligence payments commensurate with the opportunity, the level of development partner funding of clinical development and regulatory costs and ACCESS' receiving a royalty based on worldwide product revenues.

#### Scientific Background

Preclinical work to date has demonstrated that ACCESS' technology enhances the performance of therapeutic and diagnostic/prognostic imaging agents by binding them to GLYCOS carriers which rapidly target to sites of tissue disease and cause them to remain there for longer intervals while rapidly clearing the non-targeted fraction. The GLYCOS technology is patterned after an immune targeting system present in the body. GLYCOS mimic the body's defense systems and appear capable of recognizing neovascular receptors selectively at sites of disease, crossing vascular barriers and targeting drug payloads to tumor sites, infections, inflammatory lesions, cardiovascular disease and potentially other disease entities.

ACCESS' GLYCOS carriers are derived from natural sources and comprise the carbohydrate portions of natural proteoglycans. GLYCOS have favorable toxicity profiles compared to synthetic molecules. Also, currently they are the only cost effective carrier substances available in the class of complex carbohydrates. Examples of ACCESS carriers include heparin and dermatan sulfate, the former an approved substance worldwide, and the latter a product in advanced clinical development in Europe.

ACCESS has researched various GLYCOS for their targeting, biodistribution, and clearance properties. ACCESS is now able to select the combination of GLYCOS and active substances to provide optimal formulation characteristics, minimize the dose-related side effects in preclinical testing, optimize clearance rates and routes of different drugs and potentially obtain site selectivity for different major classes of disease, beginning with cancer and infection.

Importantly, the binding of drugs and imaging agents to GLYCOS carriers is typically by noncovalent physical processes. This results in simple formulations which utilize existing, approved/approvable substances as carriers and are expected to be compatible with a range of drugs and imaging agents.

ACCESS' proprietary GLYCOS carriers bind first to the body's endothelial receptors that are induced on the microvascular barrier between the bloodstream and the tissue sites of disease. Consequently, in a fashion similar to the body's own cellular immune mechanisms, ACCESS' GLYCOS formulations progressively accumulate and cross into sites of disease from their initial binding/targeting sites on induced endothelium and are able to continue such accumulation with repeated dosing, depending on the nature, severity and persistence of the disease and the tissue mediators. Being sulphated polysaccharides, these GLYCOS appear to avoid inducing anticarrier antibodies to themselves except in the extremely low incidence established for therapeutic heparinoids.

Attaching a GLYCOS carrier to a drug or imaging agent causes the drug or imaging agent to accumulate at the site of tissue damage more rapidly and to a significantly greater extent than without the GLYCOS.

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Moreover, by piggybacking on the physiological pathway that allows cells and molecules to penetrate the endothelial barrier and permeate deep into the

underlying tissue lesion, GLYCOS help bring the drug closer to all sub-regions and cells of the pathologic lesion.

ACCESS believes that both the polymeric and multivalent binding properties of GLYCOS are important for optimal disease site-localization of the attached drug or diagnostic/prognostic. These aspects are important in optimizing biodistribution, targeting and clearance and may also promote displacement of the endogenous interfering substances which can be bound to diseased endothelium, further enhancing the active endothelial translocation of the GLYCOS drug or diagnostic into underlying sites of disease.

Drug and diagnostic enhancement by ACCESS' GLYCOS occurs by a number of mechanisms, the principal ones being rapid selective targeting to tissue sites of disease, stabilization of the active substance during both storage and plasma transmit, longer retention at the site of disease and rapid clearance of the non-targeted fraction giving reduced imaging backgrounds and reduced drug toxicity.

Product Developments

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	ACCESS	DRUG PORTFOLIO		
<s> Compound</s>	<c> <c< td=""><td></td><td><c> Clinical FDA Filing</c></td><td>Stage (1)</td></c<></c>		<c> Clinical FDA Filing</c>	Stage (1)
Cancer				
AP 4010	ACCESS	Anti-tumor (Cancer)	Developmen	nt Pre-Clinical
AP 2011	ACCESS	MRI Contrast Agent	Developme	nt Pre-Clinical
Radiopharmaceutical	ACCESS	Cancer Diagnosi	s Develop	ment Research
Masoprocol(3)(5)	ACCESS	Anti-tumor (Cance	er) Develop	ment Pre-Clinic
Anti-Fungal				
AP 1110	ACCESS	Anti-fungal	Development	Pre-Clinical
Dermatology				
Actinex(TM)(2)	ACCESS	Actinic keratosis approved	FDA	Completed
Amlexanox(2) (CHX-3673)	Takeda	Oral ulcers April 1	NDA filed 995	Completed
CHX-100 (3)(5)	ACCESS photoag	Prevention of ring of skin 1993	IND filed	Phase II
Hypericin(4)(5)	VimRx	Psoriasis	VimRx IND	Phase I

#### </TABLE>

- (1) See "Government Regulations" for description of clinical stages.
- (2) Sold to Block. Subject to a Royalty Agreement.
- (3) Involves the use of NDGA and may be developed by ACCESS pursuant to the royalty-free, worldwide, exclusive license from Block to ACCESS.

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- (4) Option to license compound for dermatological use from  $VimRx\ Pharmaceuticals.$
- (5) Development currently suspended. Furthered development is under review.

ACCESS currently has rights to three drugs in various stages of human clinical development covering medical indications for the following disease states: contact dermatitits, mild to moderate psoriasis and photoaging of the skin (anti-wrinkling). ACCESS also has an option to license hypericin from Vim Rx Pharmaceuticals, Inc. for dermatological use. In addition, ACCESS' proprietary drug, masoprocol, was in preclinical studies to determine the extent of its potential in treating, in combination with other chemotherapeutic agents, multiple-drug resistant cancers.

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 pre-clinical 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 scale-up manufacturing facilities are selected in conjunction with Company consultants. ACCESS does not plan to have an extensive clinical development organization as this would be conducted by a development partner.

#### Development and Research Projects

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 when these product candidates are 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.

#### Cancer

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.

Most current drugs have significant limitations. Certain cancers are inherently unresponsive to chemotherapeutic agents, 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. As the cells acquire resistance to a specific agent, they often simultaneously become resistant to a wide variety of agents through a phenomenon known as multi-drug resistance. 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.

ACCESS' cancer program is aimed at formulating generic chemotherapy agents and proprietary products to enhance efficacy and reduce the toxicity compared with the currently available chemotherapeutics.

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## Product in Development

AP-4010 - ACCESS currently has one product in development, a GLYCOS-based doxorubicin formulation for intravenous administration.

The most widely used cancer agents are anthracyclines, such as doxorubicin, which are broadly effective against proliferating cancer cells. Anthracyclines have a number of limitations, certain cancer types are unresponsive and can cause severe toxic effects, including myelosuppression, mucositis and cumulative irreversible cardiotoxicity.

ACCESS' animal studies have shown that higher doses of the product can be tolerated with less acute toxicity and hence greater efficacy than standard doxorubicin. It is possible that AP-4010 may have a better pharmacokinetic profile than existing formulations of doxorubicin.

ACCESS is currently conducting pilot scale up of production of AP-4010 for animal toxicity testing prior to submission of an IND which ACCESS anticipates filling in approximately 12 months. The clinical indications are currently under evaluation by external company consultants.

#### Infectious Diseases

Systemic fungal infections are a major problem for patients with impaired immune defense mechanisms, particularly cancer patients, diabetics and AIDS patients. Available agents for the treatment of systemic fungal infections include amphotericin B and fluconazole. Despite the availability of these agents, serious fungal infections remain difficult to treat. Because fluconazole is not effective in treating many strains of fungi and amphotericin B toxicities remain difficult to manage at effective doses, mortality rates among such patients remain high.

## Product in Development

AP-1110 - ACCESS' product development is focused on a GLYCOS-based formulation of Amphotericin B, an effective cytocidal compound whose effectiveness and regimens are limited by severe nephrotoxicity and prolonged blood and body clearance. Amphotericin B remains the standard in the treatment of fungal

infections, however, because of nephroxicity, limitations on intensive higher dosing regimens, it is difficult to cure many deep fungal infections.

The GLYCOS formulation significantly reduces kidney toxicity by redirecting the clearance of the drug through the liver, where no new hepatotoxicity has been observed (in subacute mouse toxicity tests). The clearance in animals of amphotericin B appears accelerated from 120 hours to 24 hours with the GLYCOS formulation. Based on its improved tolerance and clearance, in animal testing it was possible to sufficiently increase the dosing and regimen intensity of the GLYCOS formulation to achieve cures in animals, whereas none could be achieved with the standard formulation.

An additional animal study to confirm the findings with a second fungal model is required prior to formulation scale-up and proceeding toward an IND. This project had been scheduled as a subsequent development, pending further definition of the market potential and the interest of a strategic partner. The Company now anticipates that this product candidate will be moved into clinical development.

#### MRI Diagnostic Agents

Preoperative diagnostic imaging technologies are used to determine the existence and the extent of disease. The principal diagnostic imaging technologies are CT Scanning and Magnetic Resonance Imaging ("MRI"). Both methods produce images that show anatomic boundaries between the tissue suspected of being malignant

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and the surrounding tissue, to reveal potential disease. Neither method gives information allowing a clear distinction of malignant from nonmalignant tissue. A more recently developed technology, immunoscintigraphy, uses a gamma-ray detection camera externally to identify internally localized radiolabeled antibodies potentially specific to certain cancers. Although immunoscintigraphy with certain radiolabeled antibodies appears capable of distinguishing malignant tumors from nonmalignant lesions and surrounding tissues, none of the external imaging technologies, including immunoscintigraphy, is effective in consistently identifying primary tumors smaller than one centimeter, in precisely locating the site or margins of the tumor, in consistently identifying all metastatic tumor nodules, or in distinguishing pre-invasive from functionally invasive tumor behaviors.

The currently available contrast agents for MRI are nonselective gadolinium based extracellular agents predominantly used in imaging the central nervous system.

ACCESS is focused on expanding the utility of MRI imaging to include body imaging by developing a site-selective intravenous contrast agent with improved localization and performance outside as well as within the central nervous system. ACCESS believes that improved site selectivity, longer site contrast with rapid blood clearance, the ability to clearly delineate tumor boundaries and metastases and the opportunity to obtain additional valuable information on prognosis, function, therapeutic response monitoring and anatomy at high resolution, could be major competitive advantages of the GLYCOS formulations.

#### Product in Development

AP-2011 - A pilot formulation utilizing the GLYCOS carrier, a chelating agent and gadolinium has been prepared and an acceptable acute toxicity profile obtained.

Prior to advancing this product candidate further, additional toxicity and animal efficacy studies are required. Encouraging initial results, including the successful, rapid contrast enhancement of tumors of the liver and nonliver tumors have been obtained in four different animal models and in three different species. Acute toxicity studies have been completed. Production of GMP materials and sub-acute toxicity testing is required before submission of an IND.

#### Radiopharmaceuticals

Given currently available technologies, diagnostic techniques such as CT, MRI and immunoscintigraphy are projected to be used by a large number of physicians to detect, stage and monitor cancer. CT and MRI currently have not effectively distinguished malignant from non-malignant tissue. Several biotechnology-based companies are developing antibody products for immunoscintigraphy in colorectal, ovarian, small cell lung, melanoma and breast cancer. Although immunoscintigraphy with antibody agents and peptides has the capacity to distinguish malignant from non-malignant tissue, none of the technologies is effective in consistently identifying tumors smaller than one centimeter or in precisely locating the site of a tumor. They only indicate that cancer may be present within a general area. Because of these limitations, the physician may frequently be making decisions concerning surgery and other therapy with incomplete information.

To date, radiopharmaceuticals have been limited to diagnostic indications and bone pain management in patients with metastatic prostate cancer. There has been little use in therapy due to the toxicities associated with the radionuclides necessary to achieve therapeutic benefits, and also due to the heterogeneity of tumor-specific antigens on tumor cells and subregions, with the prominent exception of B-cell lymphomas.

#### Diagnostic Applications

A pilot GLYCOS radiopharmaceutical diagnostic imaging agent has been prepared and tested utilizing Gallium(67). Animal studies have shown that the GLYCOS have the ability to rapidly target and permeate AT-1

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prostate tumors in grown rats. These studies also showed fast clearance by the renal route and negligible liver uptake. These characteristics support the development of radiolabeled agents for tumor imaging. The pilot studies indicate selective tumor localization of the radiolabeled agent within 5 minutes of injection allowing optimal imaging between 15 minutes and 1 hour post injection.

GLYCOS may provide the key additional information of tumor function and prognosis in a way which can improve clinical diagnosis and staging, and allow rapid early decision-making on patient management and therapeutic approaches, including intraoperative approaches.

Before advancing to preclinical development, product optimization, including the selection of a radionuclide, chelator and GLYCOS carrier, must be finalized in conjunction with an external advisory group.

#### Patents

ACCESS believes that the value of technology both to ACCESS and to potential corporate partners is established and enhanced by its strong, broad and specific 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.

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. Eight patents have issued commencing in 1990 (six U.S. and two European) and an additional eight patent applications are pending (five U.S. and three PCT).

These patents and applications broadly cover 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.

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.

The intellectual property around which API was founded was originally licensed by way of a License Agreement from the inventor and principal shareholder Dr. David Ranney. A Patent Purchase Agreement dated April 5, 1994, (the "Patent Purchase Agreement") terminated the License Agreement and provided for assignment of the rights to the original patents to ACCESS. The terms of the Patent Purchase Agreement were amended effective January 25, 1996 reducing the minimum royalty payments due to Dr. David Ranney. Additional patents covering the technology were purchased from the University of Texas system on October 31, 1990 and applied for directly by ACCESS. The technology was developed by Dr. David Ranney during his tenure at the University of Texas Southwestern Medical School which retains a royalty free non-exclusive right to use the patent rights for its own research, teaching and other educationally-related purposes. See "Certain Relationships and Related Transactions."

Dr. David Ranney has signed an Assignment of Intellectual Property Agreement whereby all rights, title and interest in and to all subsequent inventions and confidential information will become the sole and exclusive

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property of ACCESS at the earlier of the date of conception or development, while he remains an employee of ACCESS and for a period of two years after he ceases employment for inventions relating to the ACCESS technology.

Under the terms of the Patent Purchase Agreement as amended, Dr. David Ranney has retained certain rights and interests in the intellectual property, including a non-exclusive right to use the inventions and technology covered by or relating to the patents for his own research, teaching or other academic related purposes, and after he is no longer a full-time employee of ACCESS for research and development of uses or implementations of the inventions and

technology improvements. ACCESS maintains the first right to negotiate the acquisition of any new inventions or technology improvements developed by Dr. David Ranney relating to the technology. Beginning in 1994, ACCESS has agreed to pay Dr. David Ranney a royalty of three quarters of one percent (0.75%) of ACCESS' gross revenues derived from products covered by the patents and pay certain minimum payments.

In addition, the Patent Purchase Agreement, as amended, establishes certain additional rights of Dr. David Ranney. The patent assignment will terminate in the event ACCESS fails to pay the amounts due to Dr. David Ranney pursuant to the Agreement, files a petition in bankruptcy, fails to commercially develop the patents or creates a security interest in the patents without Dr. David Ranney's approval. Also, in the event that parts of the ACCESS technology are not being developed prior to January 2000, Dr. David Ranney has the right of first refusal to license or acquire at fair market value development rights to such parts of the ACCESS technology.

#### 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 GLYCOS formulations incorporate extensively tested drug substances, because the resulting GLYCOS 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 regulations which establish the minimum requirements for methods to be used in, and the facilities or controls to be used during the production process and the 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 an 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.

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Phase III trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit-to-risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA for approval to commence commercial sales.

The process of doing the requisite testing, data collection, analysis and compilation of an IND and an NDA is labor intensive and costly and may take a protracted time period. In some cases tests may have to be re-done 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 an NDA will be approved. Hence, ACCESS cannot with any certainty estimate how long the approval cycle may take.

Current U.S. government revisions to the U.S. healthcare system are not yet known in detail, but could have an impact on the pharmaceutical industry, possibly in the form of pricing restrictions. Although ACCESS is developing new novel drugs in the field of cancer and infectious disease that are currently not treated effectively, there still can be no assurance that certain pricing constraints would not pertain.

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 highly competitive. Most pharmaceutical and biotechnology companies have considerably greater research

and development, financial, technical and marketing resources than ACCESS. Although ACCESS' proposed products utilize a novel drug delivery system, they will be competing with established pharmaceutical companies' existing and planned new product introductions and alternate delivery forms of the active substance being formulated by ACCESS.

A number of companies are developing or may, in the future, engage in the development of products competitive with the ACCESS delivery system. Currently, in the therapeutic area, liposomal formulations being developed by Nexstar, Inc., The Liposome Company, Inc. and Sequus Pharmaceuticals, Inc. are the major competitive intravenous drug delivery formulations which utilize 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.

The principal current competitors to ACCESS' technology fall into three categories: monoclonal antibodies, liposomes and peptides. ACCESS believes its technology represents a significant advance over these older technologies because it is the only system with a favorable pharmacokinetic profile which has been shown to effectively bind and cross neovascular barriers and to deeply penetrate the major classes of deep tissue and organ disease, which remain partially inaccessible to older technologies.

Even if ACCESS' products are fully developed and receive required regulatory approval, regarding which there is 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 the technology will potentially be more rapidly developed and successfully introduced into the marketplace.

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#### Employees

As of March 18, 1996 ACCESS has 9 full time employees and one part time employee three of whom have advanced scientific and medical 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.

## Risk Factors

Certain of the statements contained in this Annual Report on Form 10-K are forward looking statements that involve risks and uncertainties. Such statements are subject to important factors that could cause actual results to differ materially, including the following risk factors:

Research and Development Focus ACCESS' focus is on commercializing proprietary biopharmaceutical patents. Although ACCESS is projected to have royalty income, it 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. In addition, royalties received by ACCESS for sales of Actinex(TM) and Amlexanox have not been significant 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 non-revenue producing company, normal credit arrangements are unavailable to ACCESS and, 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 arrangements would be available. Further, it is anticipated that additional losses will be incurred in the future, and there can be no assurances that ACCESS will ever achieve significant revenues.

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 due to 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.

History of Losses ACCESS has sustained net operating losses since its inception. Since the development and commercialization of current and new products will require substantial expenditures for the foreseeable future, ACCESS expects to incur further losses. If ACCESS' losses continue, its ability to continue its operations will depend upon its ability to secure additional funds. ACCESS' revenue trend and future additional cash needs may display significant variations due to the introduction of new research and development agreements and licensing arrangements, the completion or termination of those agreements and arrangements, the timing and amounts of milestone payments, and the timing of regulatory approvals and market introduction of products.

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Future Capital Requirements ACCESS will require substantial funds for its research and product development programs, the pursuit of regulatory approvals, operating expenses, working capital and expansion of its production capabilities. There can be no assurance that ACCESS will be profitable in the future and if ACCESS has insufficient funds for its capital needs, there can be no assurance that additional funds can be obtained on acceptable terms, if at all. If necessary funds are not available, ACCESS' business would be materially adversely affected.

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 early 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 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 with commercial potential that it determines to commercialize itself. There can be no assurance, however, that it will be able to acquire such resources or personnel.

Protection of Proprietary Technology ACCESS' ability to compete effectively with other companies will depend, in part, on its ability to maintain the proprietary nature of its technology. Although ACCESS has been awarded eight patents involving 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; and eight applications are pending, there can be no assurance that these patents will not be declared invalid or circumvented, or that pending patents will be issued. In addition, there may be other patents issued covering technologies and products which may be required by ACCESS to manufacture, use or sell any potential products. There can be no assurance that ACCESS could obtain a license under any such patent on commercially acceptable terms or at all. To protect their rights in these areas, ACCESS generally requires its respective employees, consultants, advisors and collaborators to enter into confidentiality agreements. There can be no assurance, however, that these agreements will provide meaningful protection for ACCESS' trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of such trade secrets, know-how or other proprietary information. Litigation may be necessary to protect trade secrets or know-how currently owned by ACCESS to determine the scope and validity of the proprietary rights of others and could result in substantial cost and diversion of effort by ACCESS.

Regulation by Government Agencies The pharmaceutical industry is subject to regulation by the FDA and comparable agencies in foreign countries prior to commercial marketing. The process of obtaining approvals from such agencies for any potential products of ACCESS can be costly, complicated and time consuming and there can be no assurance that such approvals will be granted on a timely basis, if ever. The regulatory process may delay the marketing of any new products for lengthy periods, impose substantial additional costs and furnish an advantage to competitors who have greater financial resources. In addition, the extent of potentially adverse governmental regulations which might arise from future legislative,

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administrative or judicial action cannot be determined. ACCESS cannot predict at this time what effect FDA actions may have on the approval process to which ACCESS' potential products may be subject.

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 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.

Competition The domestic and international markets for the pharmaceutical industry are highly competitive. Many of ACCESS' competitors have significantly greater financial, technical, research and development and marketing resources than ACCESS. ACCESS' ability to compete depends primarily upon scientific and technical superiority, patent protection, timely regulatory approvals and effective pricing and marketing. ACCESS' future success will also depend upon, among other factors, its ability to develop, introduce, manufacture and obtain regulatory approvals on a timely basis for new or potential products. Other substances or technologies currently existing or developed in the future may be the basis for competitive products that will render ACCESS' technology obsolete or non-competitive. There can be no assurance that any potential products or processes will compete successfully. Additionally, there can be no assurance that ACCESS' competitors will not substantially increase the resources devoted to the development and marketing of products competitive with those of ACCESS.

Dependence Upon Skilled Personnel The business of ACCESS depends heavily upon the active participation of Dr. David Ranney and Kerry P. Gray. Loss of the services of either of these individuals would adversely affect the operation of ACCESS' business. In addition, both the long and short term success of ACCESS depend in large part upon its continued ability to attract and retain skilled scientific, and managerial employees, which may prove difficult because the market for the services of such individuals is highly competitive.

#### ITEM 2. PROPERTIES

ACCESS maintains one facility of administrative offices and laboratories in Dallas, Texas. ACCESS has a lease agreement for the facility which has approximately 5,500 square feet, which terminates in January 1998 however the Company has an option for early termination. Adjacent space is available for expansion which would accommodate the growth planned for the foreseeable future.

## ITEM 3. LEGAL PROCEEDINGS

ACCESS is not a party to any legal proceedings.

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

A Special Meeting in lieu of the 1995 Annual Meeting of Stockholders of the Company was held at 10:00 a.m., January 25, 1996 to consider and vote upon proposals to (i) approve and adopt that certain Agreement of Merger and Plan of Reorganization, dated as of October 3, 1995, as amended and restated as of October 31, 1995 (the "Merger Agreement") by and between the Company and API, pursuant to which, among other matters, API would be merged with and into the Company with the Company the surviving corporation (the "Merger") and each share of API's common stock, \$.01 par value per share, would be converted into approximately 3.7744 shares

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of the Company's common stock, \$.04 par value per share ("Company Common Stock") (subject to adjustment as provided in the Merger Agreement); (ii) approve an amendment to the Certificate of Incorporation of the Company increasing the number of authorized shares of the Company Common Stock to 40,000,000 shares and the number of authorized shares of the preferred stock, \$.01 par value per share, of the Company to 10,000,000 shares; (iii) approve an amendment to the Certificate of Incorporation of the Company to effect a change of the name of the Company from Chemex Pharmaceuticals, Inc. to "ACCESS Pharmaceuticals, Inc."; (iv) approve the establishment of the ACCESS 1995 Stock Option Plan (the "1995 Stock Option Plan"), under which an aggregate of 2,000,000 shares of ACCESS Common Stock will be issuable pursuant to the terms of such plan; (v) ratify the selection by the Board of Directors of ACCESS of ACCESS' independent auditors; (vi) elect three directors; and (vii) approve an adjournment of the Special Meeting, if necessary, to permit further solicitation of proxies in the event that there are not sufficient votes at the Special Meeting to consider and approve any or all of the above proposals. All proposals were approved by the stockholders.

The voting with respect to each of such matters was as follows:

Item 1	For	Withhold
Greetham Taylor Woolard	7,587,633 7,586,547 7,587,633	232,047 233,133 232,047
	For	Against
Item 2	5,146,576	49,075
Item 3	5,097,671	84,407
Item 4	7,708,188	62,635
Item 5	4,849,452	537,159
Item 6	7,717,348	65,156

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#### PART II

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

During the time periods shown on the table below, ACCESS' Common Stock was traded on the National Association of Securities Dealers, Inc. Automated Quotation System ("Nasdaq") SmallCap market under the trading symbol CHMX until April 27, 1995. ACCESS' securities were delisted from the Nasdaq SmallCap Market on April 27, 1995 for failure to meet certain financial requirements. ACCESS Common Stock now trades on Nasdaq Over-the-Counter ("OTC") Bulletin Board and as of February 1, 1996 trades under the trading symbol AXCS. The following tables set forth the high and low closing prices for ACCESS' Common Stock for the periods indicated as reported by Nasdaq.

	Commo	
	High	Low
Fiscal Year Ended December 31, 1995		
First quarter Second quarter (1) Second quarter (2) Third quarter Fourth quarter	3/4 1/2 9/16 19/32 1-1/8	1/1
Fiscal Year Ended December 31, 1994		
First quarter Second quarter Third quarter Fourth quarter	1-13/16 13/16 1 11/16	5 1/8 9/16

- (1) Through April 27, 1995 on NASDAQ SmallCap Market.
- (2) After April 27, 1995 on OTC Bulletin Board.

The number of record holders of ACCESS' Common Stock at March 18, 1996 was approximately  $3{,}000$  and the closing price on that date was \$2.5625.

In January, 1996 the stockholders authorized an increase from five to ten million shares of preferred stock as part of the Company's merger with API. To date, no preferred shares have been issued.

ACCESS has never paid any cash dividends on its ACCESS Preferred Stock or Common Stock. The payment of dividends, if any, in the future is within the discretion of the Board of Directors and will depend upon ACCESS' earnings, its capital requirements and financial condition, and other relevant facts. ACCESS does not plan any cash dividends in the near future.

ACCESS was notified by Nasdaq on April 26, 1995 that its request for a temporary exemption from certain continued listing financial requirements was denied. ACCESS has been de-listed from the Nasdaq Small-Cap Market and the ACCESS Common Stock now trades on the OTC Bulletin Board under the sale stock symbol "AXCS." ACCESS' appeal to Nasdaq's decision was denied on July 31, 1995. ACCESS plans to reapply when Nasdaq qualifications are met.

ITEM 6. SELECTED FINANCIAL DATA (Thousands, Except for Net Income (Loss) per Share)(1)

As of or for the Year Ended Dece	ember 31,	1995	1994	1993	1992	199
<s> Balance Sheet Data:</s>	<c></c>	<c> &lt;</c>	<c> ·</c>	<c></c>	<c></c>	
Datance Sheet Data.						
Total Assets	\$2,129	\$1,704	\$3,016	\$6,535	\$1,676	
Total Liabilities	443	377	986	1,010	890	
Stockholders' Equity	1,686	1,327	2,030	5,525	786	
Income Statement Data:						
Total Revenues	2,945	3,162	1,656	9,046	3,103	
Total Expenses	2,604	4,121	5,223	4,361	3,783	
Net Income (Loss)		(959)	(3,567)	4,254	(680)	
Common Stock Data(2).						
Net Income (Loss) Per Shar	re .	.04 (.11	) (.43)	.48	(.08)	
Average Number of Comm Shares and Common Equiv						
Shares Outstanding	8,717	8,543	8,385	8,843	8,107	

- (1) Does not reflect the merger of ACCESS Pharmaceuticals, Inc., a Texas corporation, with and into the Company on January 25, 1996
- (2) Restated to reflect the 1992 one for four reverse stock split and 100% stock dividend

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

## Overview

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

Until July 1995 and the sale of the drug Amlexanox to Block, ACCESS focused on the development of novel drugs for the treatment of various skin diseases and had a diversified portfolio of drugs under development.

As consideration for the sale of ACCESS' share of Amlexanox, Block (a) made an initial non-refundable upfront royalty payment of \$2.5 million; (b) is obligated to pay to ACCESS \$1.5 million as a prepaid royalty at the end of the calendar month during which Block together with any sublicensee has achieved cumulative worldwide sales of Amlexanox oral products of \$25 million; and (c) after the payment of such \$1.5 million royalty, is obligated to pay ACCESS a royalty on all sales in excess of cumulative worldwide sales of Amlexanox oral products of \$45 million, as defined in the agreement.

ACCESS' obligations following such sale are limited to performing reasonable activities in support of obtaining FDA approval of Amlexanox until the earlier of (i) three years after FDA approval of Amlexanox, or (ii) the liquidation or dissolution of ACCESS. An NDA for Amlexanox was filed in April 1995 and the Company is awaiting approval of this product. As a result, there have been no sales of Amlexanox to date.

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 parental therapeutic and diagnostic imaging agents through the utilization of its patented and proprietary endothelial binding technology which selectively targets sites of disease.

ACCESS Pharmaceuticals is an emerging pharmaceutical company with a broad platform technology for enhancing the site targeting of intravenous therapeutic drugs, MRI contrast agents and radiopharmaceutical diagnostic and therapeutic agents. The ACCESS technology is based on natural carbohydrate carriers.

The technology development of ACCESS is currently focused on increasing the therapeutic benefit of oncology agents and improving the efficiency of oncology diagnosis by selectively targeting sites of disease and accelerating drug clearance

ACCESS has developed four possible product candidates, two of which are believed ready to be advanced into human testing. These product candidates are new formulations of existing compounds which increase therapeutic efficacy and reduce toxicity, designed to address the clinical shortfalls of available treatments

Forward-looking narratives included herein are subject to and should be read in conjunction with the "Risk Factors" section of this Form 10-K.

Liquidity and Capital Resources

Working capital as of March 18, 1996 was \$6,559,000, an increase of \$4,866,000 as compared to the working capital as of December 31, 1995 of \$1,693,000. The increase in working capital was principally due to the \$6 million private placement of 8.57 million shares of common stock concluded in March 1996. The cash infusion will be used to continue the advancement of the product portfolio which focuses on increasing the therapeutic benefit and improving the efficiency of oncology therapeutics and diagnostic agents by selectively targeting sites of disease and accelerating drug clearance. The shares issued in the private placement have not been registered, however the Company has agreed to file a registration statement within 90 days of the date of

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issuance. The investors have agreed not to sell any of the shares purchased in the offering until 180 days after the closing.

Management believes its working capital will cover planned operations through December 1997.

There are no royalty revenues expected during 1996 but there are planned research and development expenditures to advance products into human testing. Expenditures will remain high for several years and there can be no assurance that the Company will be successful in attaining a partner or future equity financing to complete the testing of its products.

Results of Operations

Comparison of Years Ended December 31, 1995 and 1994

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Net Revenues for the twelve months ended December 31, 1995 were \$2,945,000, \$217,000 lower than the 1994 comparable period. The change in revenues from year to year is explained as follows: the one-time non-refundable receipt of upfront royalties in 1995 for the sale of Amlexanox rights by the Company to Block of \$2,500,000, offset by the one-time sale of 10% of a Joint Venture between the Company and Block in the amount of \$1,700,000 in June 1994; and the reduction from 1994 to 1995 of joint venture/Amlexanox project research revenues of \$981,000 principally due to the termination of the ACCESS/Block Joint Venture in December 1994 which effectively reduced research reimbursement (of 50%) of a majority of the Company development projects (with the exception of Amlexanox which was funded 50/50 until the sale of Amlexanox rights by the Company to Block in September 1995).

Research and development expenses were \$1,253,000 for the twelve months ended December 31, 1995 as compared to \$2,591,000 for the same period in 1994. The reduction of overall research and development spending in 1995 from 1994 of \$1,338,000 was principally due to the completion of Phase III clinical trials in the third quarter of 1994 for Amlexanox which was the most expensive phase in the development of the drug. The Company terminated all other research and development during the third quarter of 1995 in anticipation of the proposed merger of API with and into the Company.

Effective July 1, 1995, operating expenses were reduced to a minimum in contemplation of the Merger. Operating expenses were \$1,341,000 in 1995, a reduction of \$40,000 as compared to the prior year. The change in spending may be summarized as follows: the elimination of litigation fees which were incurred in 1994-\$131,000; lower compensation expenses in 1995 due to a voluntary salary reduction of the CEO/Chairman and elimination of positions-\$135,000; the elimination of investment banking fees incurred in 1994-\$92,000; the elimination of product liability insurance in 1995-\$29,000; offset by higher legal fees due to the termination agreement for the Joint Venture and the agreement to sell the rights to Amlexanox to Block-\$174,000; professional fees related to the merger-\$140,000; and the settlement as to the termination of the New Jersey lease-\$79,000.

Professional fees-related party were \$13,000 for the twelve months ended December 31, 1995, a reduction of \$14,000 from the prior year.

Stock awards decreased \$125,000 in 1995 as no such awards were granted in 1995.

Accordingly, total expenses were \$2,604,000 for 1995, a reduction of \$1,517,000 from 1994

Comparison of Years ended December 31, 1994 and 1993

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In June 1994, the Company sold 20% of its share of the Joint Venture (or 10% of the total Joint Venture) to Block for \$1,700,000. Effective December 31, 1994, the Company re-acquired its 10% ownership of the

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Joint Venture from Block in return for giving certain proprietary rights to Amlexanox to Block. The effect of the December transactions was to allow the Company to retain the \$1.7 million it had received in June 1994. The Joint Venture was then dissolved. The dissolution of the Joint Venture established the transfer of the following ownership rights: the Company returned its rights to Penederm's retinoic acid product (Acticin) to Block, which had been sublicensed to the Joint Venture by Block: Block returned its share of the ownership of the balance of the dermatology drug portfolio to ACCESS (CHX-100, CHX-108, and EPC-K1); and Block and the Company entered into a joint ownership arrangement for Amlexanox. Accordingly, total 1994 revenues were \$3,162,000, an increase of \$1,506,000 over 1993. Partially offsetting the one time sale of rights for \$1,700,000 was the following: a net reduction in Joint Venture billing principally due to projects canceled in 1994 as compared to 1993-a reduction of \$97,000; lower interest income due to an average lower level of cash on hand-\$74,000; and lower royalty income for Actinex due to disappointing sales results by Block-\$23,000.

Total research and development expenses were \$2,591,000 for 1994, a reduction of \$315,000 as compared to fiscal 1993. The reduction of spending was in part due to lower spending associated with Joint Venture projects (down \$233,000) which is due to a net change in spending by project as follows: Amlexanox-up \$234,000 due to completion of Phase III studies; EPC-K1-down \$29,000 as the program was delayed due to the decision by the FDA that the compound could not be studied in adolescents as planned; PAF Antagonist-down \$210,000 due to the discontinuance of the project in late 1993; CHX-100-increase of \$224,000 due to the commencement of studies in photoaging; and Zinc/Durascreen-down \$278,000 due to the cancellation of these projects. Projects outside the Joint Venture totaled \$153,000 in 1994 a reduction of \$171,000 as compared to 1993. The decrease is principally due to the cancellation of Cytarabine which had been studied as a treatment for genital warts which was discontinued in late 1993.

General and administrative operating expenses were \$1,381,000 in 1994, a reduction of \$514,000 as compared to 1993. The reduction was due to a number of cost reduction activities implemented in late 1993 which positively impacted 1994. A summary of the principal expense reductions are as follows: lower compensation of \$144,000 chiefly due to a reduction in the Chief Executive Officers' salary of \$42,000 and the elimination of bonuses paid to executive officers of \$92,000; the elimination of the use of public relations firm and the elimination of developing a formal annual report-savings of \$118,000; and the elimination of litigation legal fees resulting from the settlement of a lawsuit against three former directors/officers-savings of \$194,000; and a reduction in other outside legal fees-\$46,000.

Related party professional fees decreased from \$108,000 in 1993 to \$27,000, and in 1994 a further reduction of \$81,000. The reduction was principally due to legal fees to a former directors' law firm, which firm's services were terminated in July 1993.

Amortization of stock awards was an expense in 1994 of \$122,000, and represented the difference in the fair market value of the Company's common stock as of the date of grants of SARs which were issued in 1994 at zero value. SARs were issued to employees who were not corporate officers in lieu of a cash bonus, and to corporate officers which are to vest based on certain performance criteria. For financial statement purposes, the excess of the market value over the zero exercise price was expensed in 1994. In 1993, amortization of stock awards was a credit of \$161,000, which reflected the difference between the stock price of the common stock on the date that certain SARs were exercised and the market value of the SARs as originally expensed.

In March 1994, the Company contributed \$475,000 to the final settlement of a lawsuit against three former officers/directors. This amount had been accrued in fiscal 1993.

Total expenses were \$4,121,000 for fiscal 1994, as compared to \$5,223,000 in 1993, a reduction of \$1,102,000. The net loss in 1994 was \$959,000 or a reduction in loss of \$2,608,000 from 1993. The reduction in net loss for 1994 as compared to 1993 was principally due to the sale of proprietary rights to Block for \$1,700,000; the reduction of certain litigation expenses of \$475,000; and the net effect of general cost reductions.

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as compared to a net loss of \$3,567,000, or \$.43 loss per common share in 1993.

API ---

Since the company merged with API in January 1996 in a transaction accounted for as a "reverse acquisition," management is including a brief summary of API's operations for the past two years.

The following summarizes API's results of operations for the years indicated:

Years Ended December 31,
----1995 1994
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Revenues \$845,000 \$1,048,000

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Expenses

1,348,000 1,524,000 -------Net loss (\$703,000) (\$476,000)

Revenues in 1995 were \$845,000, as compared to the same period in 1994 of \$1,048,000, a reduction of \$203,000. The lower revenues in 1995 are due to a project cancellation in June 1995 by a pharmaceutical company.

Research and development expenses for 1995 were \$675,000 as compared to \$714,000 for the same period in 1994, a decrease in spending of \$39,000. The decrease is due mainly to reduced project activity from the cancellation of a project by a pharmaceutical company which funded part of the costs. Research and development expenses are expected to increase in 1996 due to the funding received from the \$6 million private placement in March 1996 (see Liquidity and Capital Resources).

Other expenses for 1995 were \$57,000 higher than the comparable 1994 period. Expenses are generally higher due to costs associated with higher patent costs-\$43,000 associated with increased technology development and higher royalty costs; higher scientific consulting costs-\$34,000 due to costs to evaluate the API projects; higher rent and maintenance-\$15,000 due to increased rent under the rental agreement; offset by lower investment banker costs-\$43,000 due to the termination of the investor banker relationship and lower travel cost-\$15,000 due to less travel as a result of the cancellation of the R&D project by a pharmaceutical company. Other expenses are anticipated to increase in 1996 as compared to 1995. Most of the emphasis will be on research and development for the company's products.

SFAS No.123, "Accounting for Stock-Based Compensation", issued in October 1995, established financial accounting and reporting standards for stock-based employee compensation plans. These plans include all arrangements by which employees receive shares of stock or other equity investments of the employer or the employer incurs liabilities to employees in amounts based on the price of the employer's stock. This statement also applies to transactions in which an entity issues its equity instruments to acquire goods or services from non-employees. The Company will select the disclosure requirements only of FASB 123 and such additional disclosure requirements are not effective for the Company until 1996.

## ITEM 8. FINANCIAL STATEMENTS 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

There has been no Form 8-K filed within 24 months prior to the date of the most recent financial statements reporting a change of accountants or reporting disagreements on any matter of accounting principle, practice, financial statement disclosure or auditing scope or procedure.

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PART III

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

Officers and Directors

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<TABLE> <CAPTION>

Name Age

<S> <C> <C>

Herbert H. McDade, Jr. 68 Chairman of the Board of Directors

Kerry P. Gray 43 President, Chief Executive Officer, Treasurer, Director

David F. Ranney, M.D. 53 Executive Vice President, Director

Stephen B. Thompson 42 Chief Financial Officer

J. Michael Flinn 61 Director

Elizabeth M. Greetham 46 Director

</TABLE>

Business and Experience of Directors and Executive Officers

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The Board of Directors of the Company is divided into three classes. Members of each class serve a term of three years until the respective annual meeting of stockholders and election and qualification of their successors. There are currently no members of Class 1 whose term expires upon the Annual Meeting of Stockholders in 1996. Dr. David F. Ranney and Elizabeth M. Greetham are Class 2 directors to serve as such until their successors shall be elected and qualified. Messrs. Gray, McDade and Flinn are Class 3 directors to serve as such until the 1998 Annual Meeting of Stockholders and until their successors shall be elected and qualified. Each officer of the Company is selected by the Board of Directors for a term of one year. There is no family relationship among any of the Directors or Executive Officers.

Mr. Herbert H. McDade, Jr. was elected a Director of the Company in January 1988. In February 1989, he was elected Vice-Chairman of the Board of Directors and Chief Executive Officer of the Company. In June 1989, he was elected Chairman of the Board of Directors and Treasurer in addition to his responsibilities as Chief Executive Officer, and in May 1990 he assumed the position of President of the Company, Mr. McDade served in such capacities until January 25, 1996. He is also a member of the Audit & Finance and Compensation Committees of the Board of Directors. He is currently President and Chief Executive Officer of the Thoma Corporation, a closely-held health care consulting company. In addition, he also serves on the Boards of CytRx Corporation, Shaman Pharmaceutical Co., Vaxcel Inc. and Clarion Pharmaceuticals, Inc. From 1986 to 1987 he served as Chairman of the Board of Directors and President of Armour Pharmaceutical Co., a wholly-owned subsidiary of Rorer Group, Inc. Prior to 1986 he served for approximately 13 years in various executive positions at Revlon, Inc., including President of the International Division of the Revlon Health Care Group from 1979 to 1986. He was also previously associated for twenty years in various executive capacities with The Upjohn Company. From January 1989 to July 1995 he served on the Board of API.

Mr. Kerry P. Gray, has been President and a Chief Executive Officer and a Director of the Company since January 25, 1996. Prior to such time he served as President and Chief Executive Officer of API since June 1993. Previously, Mr. Gray served as Vice President and Chief Financial Officer of PharmaSciences, Inc., a company he co-founded to acquire technologies in the drug delivery area. From May 1990 to August 1991, Mr. Gray was Senior Vice President, Americas, Australia and New Zealand of Rhone-Poulenc Rorer, Inc.

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Prior to the Rorer/Rhone Poulenc merger, he had been Area Vice President Americas of Rorer International Pharmaceuticals. Previously, from January 1986 to May 1988, he was Vice President, Finance of Rorer International Pharmaceuticals, having served in that same capacity for the Revlon Health Care Group of companies before their acquisition by Rorer Group. Between 1975 and 1985, he held various senior financial positions in Revlon Health Care Group. Mr. Gray's experience in the pharmaceutical industry totals 20 years.

David F. Ranney, M.D., has been Executive Vice President and a Director of the Company since January 25, 1996. He was the founder and Chairman of the Board of Directors of API since inception in 1988, and was Executive Vice President commencing August 1995 and Vice President, Research and Development since June 1993. Previously, he was President and Chief Executive Officer of API since founding API in March 1988. Until November 1989, Dr. Ranney directed the Laboratory of Targeted Diagnosis and Therapy at the University of Texas Southwestern Medical Center, where he held a joint faculty appointment in Radiology and Pathology. Dr. Ranney received a B.A. degree in Chemistry from Oberlin College and an M.D. from Case Western Reserve Medical School. He has postdoctoral training in Biochemistry (Case Western Reserve), Cardiovascular and Microvascular Surgery (Stanford University Medical Center), Immunology and Cancer Biology (NIH), and Pathology (University Of Texas Southwestern Medical Center).

Mr. Stephen B. Thompson, has been Chief Financial Officer of the Company since January 25, 1996. Previously from November 1990 he was Controller and Administration Manager of API. From 1989 to 1990, he was Controller of Robert E. Woolley, Inc. a hotel real estate company where he was responsible for accounting, finances and investor relations. Previously, from 1985 to 1989, he was Controller of OKC Limited Partnership, an oil and gas company where he was responsible for accounting, finances and SEC reporting. Between 1975 and 1985 he

held various accounting and finance positions with Santa Fe International Corporation.

Mr. J. Michael Flinn has served as a Director of the Company since 1983. He also is a member of the Audit & Finance and Compensation Committees of the Board of Directors. Since 1970 he has been an investment counselor. He is a principal with the investment counseling firm of Sirach Capital Management, Inc. He assists in the management of pension, profit sharing, individual, corporate and foundation accounts totaling over \$4.5 billion.

Mrs. Elizabeth M. Greetham has served as a Director of the Company since 1992 and is President of Libracorn Financial Consultants. One of her present clients is Weiss, Peck & Greer, a New York-based money management firm. With over twenty years of worldwide experience as a health care analyst and portfolio manager, she currently is responsible for Weiss, Peck & Greer's health care investments for institutional, mutual, and selected individual accounts. Prior to her association with Weiss, Peck & Greer, Mrs. Greetham consulted for a number of years for F. Eherstadt & Co., a New York institutional brokerage house. She is a member of the Board of Directors of Repligen Corporation, a pharmaceutical development company. She is a member of the Company's Audit & Finance and Compensation Committees.

Compliance with Section 16(a) of the Securities Act of 1934

Section 16(a) of the Securities Exchange Act of 1934 requires the Company's Directors, Executive officers and persons who own more than ten percent of a registered class of the Company's equity securities ("10% holders"), to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company. Directors, officers and 10% holders are required by SEC regulation to furnish the Company with copies of all of the Section 16(a) reports they file.

Based solely on a review of reports furnished to the Company or written representatives from the Company's Directors and executive officers during the fiscal year ended December 31, 1995, all Section 16(a) filing requirements applicable to its Directors, officers and 10% holders for such year were complied with.

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#### ITEM 11. EXECUTIVE COMPENSATION

Each Director who is not an employee of the Company receives the sum of \$500 for each meeting of the Board of Directors attended. Each Director who is not an employee of the Company but is a member of the Executive Committee or the Audit and Finance Committee receives the sum of \$400 for each committee meeting attended.

Summary Compensation Table

- -----

The following table sets forth the aggregate compensation paid by the Company to each of the most highly compensated executive officers of the Company whose aggregate salary and bonus exceeded \$100,000 for services rendered in all capacities to the Company for the year ended December 31, 1995.

<TABLE> <CAPTION>

#### Long-term Annual Compensation Compensation Awards Name and Securities Underlying All Other Principal Position Year Salary(1) Bonus Options/SARs (#) Compens. <S> <C> <C> <C> <C> <C> Herbert H. McDade, Jr. 1995 \$110,571 \$ 0 \$57,165(2) 1994 Chairman & Former CEO(5) 226,829 46,122(2) 131,714 174,000 62,500 50,000 60,371(2) 1995 \$103,751 \$ 0 Atul S. Khandwala 0 \$57,173(6) 153,960 107,715 Former Executive Vice 1994 19,620(4) 1993 President(5) 160,626 30,519 25,000 28.662(3)

- These amounts are prior to reduction for deferred employer contributions under the Company's Employee Stock Ownership Plan Pursuant to Section 401(k) of the Internal Revenue Code of 1986, as amended (the "Code").
- Pursuant to Mr. McDade's employment agreement, Mr. McDade was reimbursed for certain expenses. In 1995, he was reimbursed for

insurance payments (\$49,682) and auto allowance (\$6,000) and auto insurance reimbursement (\$440). In addition, the Company made ESOP contributions in stock of \$1,043. In 1994, he was reimbursed for life insurance payments (\$23,000) and auto allowance (\$6,000) and auto insurance reimbursement (\$658). In addition, the Company made ESOP contributions in stock of \$16,464. In 1993, he was reimbursed for life insurance payments (\$31,220) and auto allowance (\$6,000) and auto insurance reimbursement (\$1,254). In addition, the Company made ESOP contributions in stock of \$21,897.

- Represents Company ESOP contributions in stock of \$20,560 and relocation expenses of \$8,102.
- (4) Represents Company ESOP contributions made in stock.
- (5) Effective January 25, 1996 and August 31, 1995, Mr. McDade, Mr. Khandwala, respectively, resigned as officers of the Company. Mr. McDade remains as Chairman of the Board of Directors.
- (6) Pursuant to Mr. Khandwala's severance agreement payments of \$53,542 were made to during 1995. Represents company ESOP contributions made in stock of \$3,631.

</TABLE>

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### Options/SARs Year-End Value Table

This table includes the number of shares covered by both exercisable and non-exercisable stock options/SARs as of December 31, 1995. Also reported are the values for "in-the-money" stock options/SARs which represent the positive spread between the exercise price of any such existing stock options/SARs and the year-end price of the Company's common stock. There were no SARs granted or exercised by the officers during 1995.

<TABLE> <CAPTION>

AGGREGATED OPTION/SAR EXERCISES IN LAST FISCAL YEAR AND FY-END OPTION/SAR VALUES

Number of Value of
Securities Underlying Unexercised InUnexercised The-Money
Shares Acquired Value Options/SARs at Options/SARs at

Shares Acquired Value Options/SARs at Options/SARs at on Exercise (#) Realized (\$) Fiscal Year-End (#) Fiscal Year-End (\$)

Exercisable/ Exercisable/ Unexercisable
Unexercisable
Unexercisable

			Unexercisable	Unexercisable	
<s> H. McDade, Jr.</s>	<c></c>	<c></c>	<c> 490,004/0</c>	<c> \$184,756/\$0</c>	
A. Khandwala	-	-	268,965/0	\$73,572/\$0	

</TABLE>

Long-Term Incentive Awards Table

Not applicable.

Compensation Pursuant to Agreements and Plans

**Employment Agreements** 

Mr. Herbert H. McDade, Jr. Effective February 1, 1989 the Company and Mr. McDade entered into an employment agreement, as amended (the "McDade Agreement"), which provided that he would serve as the Chief Executive Officer of the Company and Vice Chairman or Chairman of the Board of Directors. The McDade Agreement was amended, effective June 25, 1991, to provide for a term ending June 30, 1994, and was extended to January 31, 1996. Mr. McDade left the company as President and Chief Executive Officer on January 25, 1996 after the Merger was completed. See Item 13 Certain Relationships and Related Transactions - Transactions with Management and Others. Mr. McDade was eligible to participate in all company employee benefit and welfare programs available to executives. The Company also paid insurance premiums on \$1 million of life insurance payable to his estate, medical expenses coverage for Mr. McDade and his spouse and long-term disability coverage for Mr. McDade. The McDade Agreement provided that, upon termination, a cash severance payment equal to one year's salary would be paid if Mr. McDade was terminated by the Company without cause and a cash severance equal to two years' salary would be paid if he terminated his employment for good reason. Mr. McDade waived the severance provisions when leaving the company.

Pursuant to the McDade Agreement and in accordance with the Company's 1987 Stock Awards Plan, the Company granted to Mr. McDade (i) on February 1, 1989 options (the "February Options") for the purchase of 50,000 shares of common stock, and (ii) on December 31, 1989 options ("the December Options") for the purchase of 37,500 shares of common stock, upon vesting and payment of the exercise price. The February

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Options and December Options are referred to collectively herein as the "New Options." On July 31, 1991, Mr. McDade exchanged 87,500 previously granted options for 80,625 New Options. The New Options are identical to the exchanged options, except that the New Options have a lower exercise price. All of the New Options have vested. On March 31, 1992, Mr. McDade was granted 65,000 options at market value, which have vested as of December 31, 1994. On July 29, 1993, Mr. McDade was granted 50,000 options at market value, which vest based on certain performance criteria. On April 29, 1994, Mr. McDade voluntarily accepted a salary reduction of approximately \$64,000 on an annualized basis. In exchange for this salary reduction, Mr. McDade was granted 75,000 options at market value, to vest in one year from the date of the grant. On July 29, 1994, Mr. McDade was granted 50,000 options, which vest based on certain performance criteria, all of which have vested. On December 31, 1994, Mr. McDade was granted 101,829 SARs with zero base value or exercise price, based on certain performance criteria. Upon Mr. McDade's termination of employment (other than termination by the Company for cause or by Mr. McDade without good reason), all options shall immediately vest and become exercisable. All Options and SARS are vested. Mr. McDade also holds 17,550 vested options for the purchase of common stock granted pursuant to the Non-Employee Directors Stock Option Plan. Mr. McDade has the right to request (subject to certain limitations by the underwriters) that all shares of common stock which he owns or may acquire in the future be included in registration statements of company securities filed with the Securities and Exchange Commission.

The McDade Agreement also contained a provision for stock appreciation rights ("SARS") pertaining to 50,000 shares of common stock with a zero base value or exercise price. All of the stock appreciation rights have vested. Appreciation on SARs is to be paid in shares of common stock; as of December 31, 1991, Mr. McDade waived his right under the provision of the 1987 Stock Awards Plan to request the Board to authorize a cash payment for any SARs he elects to exercise.

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

The following table sets forth beneficial ownership of Common Stock as of February 29, 1996 by all Directors and named Executive Officers of the Company and all Directors and Executive Officers as a group, and all owners of 5% or more of the Common Stock:

#### Common Stock Beneficially Owned

Name	Number of Shares (1)	% of Class
Herbert H. McDade. Jr.	1,008,062 (2)	4.1%
Kerry P. Gray	1,070,790	4.7%
David F. Ranney	9,147,608	40.4%
Stephen B. Thompson	55,451	.2%
Michael Flinn	63,500(3)	.3%
Elizabeth M. Greetham	32,667 (4)	.1%
David Blech and Certain Rel	ated Parties 2,275,70	00 (5) 9.5%

All Directors and Executive Officers as a group (consisting

of 6 persons) 11,378,078 49.0%

- Includes common stock held plus all options and warrants exercisable within 60 days after February 1, 1996. Unless otherwise indicated, the persons listed have sole voting and investment powers with respect to all such shares.
- (2) Including presently exercisable options for the purchase of 17,550 shares of Common Stock pursuant to the Non-Employee Director Plan, and 320,625 shares of Common Stock and 151,829 SARs exercisable pursuant to the 1987 Stock Option Plan and 69,270 shares issued in connection with the ESOP.
- (3) Including presently exercisable options for the purchase of 54,000 shares of Common Stock pursuant to the Non-Employee Director Plan.
- (4) Including presently exercisable options for the purchase of 26,667 shares of Common Stock pursuant to the Non-Employee Director Plan.

(5) Sentinel Charitable Remainder Trust ("Sentinel"), 599 Lexington Avenue, New York, New York, is known to ACCESS to be the beneficial owner of more than five percent of the Common Stock. Mr. David Blech is the direct and indirect owner of 1,075,700 shares of Common Stock which represents 4.75% of the outstanding shares of Common Stock as of January 31, 1996. Of such shares, 5,000 (.02%) are owned directly by Mr. Blech, 1,020,000 (4.5%) are owned by Sentinel, 25,950 (.12%) are owned by Lake Charitable Remainder Trust and 24,750 (.11%) are owned by Ocean Charitable Remainder Trust, Mr. Blech is the sole income beneficiary of the trusts, and as such may be deemed to be the beneficial owner of the securities held by them. Mr. Nicholas Madonia is the trustee of the trusts and as such may be deemed to be a beneficial owner of the securities held by them.

In addition to the 1,020,000 shares of Common Stock held by Sentinel, Sentinel additionally has an option to purchase until January 1, 1999, up to 500,000 units at \$2.50 per unit. The units consist of 500,000 shares of Common Stock, 500,000 warrants with an expiration date of January 1, 2000 and an exercise price of \$6.25 and 200,000 Warrants with an expiration date of January 1, 2000 and an exercise price of \$2.50. Information is based on Form 4 as filed by D. Blech in October 1994.

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

Transactions with Management and Others

Mr. David Blech. Mr. Blech became a financial consultant to ACCESS on October 1, 1990. His contract terminated in 1991 and under the terms of the agreement, ACCESS paid Mr. Blech \$75,000 in 1991 and \$25,000 in 1990. In 1992, Mr. Blech performed consulting services for ACCESS and ACCESS paid him \$50,000. In addition, ACCESS paid \$25,000 to Mr. Blech in January 1995 for consulting services rendered.

As of December 14, 1995, ACCESS, D. Blech & Co., and Sentinel Remainder Trust (each affiliates of Mr. Blech), entered into a Letter Agreement which provided that Sentinel Remainder Trust would forfeit its rights to representation on the Board of Directors of ACCESS in consideration of the extension of the expiration date of (i) 500,000 Units exercisable in the aggregate for 500,000 shares of Common Stock and warrants exercisable in the aggregate for 700,000 shares of Common stock pursuant to the terms of the Conversion Agreement from July 31, 1996 to January 1, 1999 and (ii) the warrants underlying the Units from July 31, 1997 to January 1, 2000.

As of January 29, 1996, ACCESS has retained Mr. Blech as a consultant to the Company for one year to advise on structuring transactions including equity placements, licensing agreements and research and development collaborations. Under the terms of the agreement Mr. Blech was paid \$480,000 and received warrants to purchase 600,000 shares of Common Stock at an exercise price of \$1.00 per share exercisable until the year 2000.

As of February 29, 1996, Mr. Blech is the direct and indirect owner of 1,075,700 Shares of Common Stock which represents 4.75% of the outstanding Shares of Common Stock. Additionally Sentinel a related party of Mr. Blech has an option to purchase until January 1, 1999, up to 500,000 units which consist of 500,000 shares of Common Stock and 700,000 warrants with an expiration date of January 1, 2000. See "Security Ownership of Certain Beneficial Owners and Management.

Dr. David Ranney. Dr. David Ranney, the Executive Vice President and a Director of ACCESS beneficially owns, approximately 9,147,608 shares of Common Stock. See "Management and Security Ownership of Certain Beneficial Owners and Management." Dr. David Ranney and ACCESS have entered into a Stockholder's Agreement providing for, among other matters, (1) certain rights of Dr. David Ranney to be nominated or to have his nominee nominated for election to the Board of Directors of ACCESS at any election of ACCESS Directors; (2) a right of first refusal of Dr. David Ranney to license or purchase certain technology and intellectual property of ACCESS under certain conditions; and, (3) a certain Patent Purchase Agreement, dated as of April 5, 1994, as amended January 25, 1996 between Dr. David Ranney and ACCESS, regarding certain royalties payable to Dr. David Ranney relating to certain technology and intellectual property of ACCESS and an agreement, subject to certain conditions, by Dr. David Ranney not to sell, transfer or otherwise dispose of his shares of the capital stock of ACCESS through July 25, 1996. ACCESS has agreed to pay Dr. David Ranney a royalty of three quarters of one percent ((0.75%) of ACCESS' gross revenues derived from products covered by the patents and pay certain minimum payments.

Herbert McDade. In consideration for the termination of his employment with ACCESS, Mr. McDade and ACCESS entered into an agreement on October 4, 1995, pursuant to which, among other things, (i) Mr. McDade became a consultant to ACCESS, providing consulting services to ACCESS at least four days each month; (ii) Mr. McDade is paid a base of \$1,500 per day of consulting; (iii) ACCESS will use its best efforts to retain Mr. McDade's enrollment under its healthcare plan and (iv) the period for exercise of all options and SARs owned by Mr. McDade was extended from three months after the termination of his employment with ACCESS to the expiration of the option or SAR. See "Security Ownership of Certain Beneficial Owners and Management."

#### PART IV

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

<TABLE> <CAPTION:

PTION>	
<s></s>	Page
Financial Statements. The following financial statements are submitted as part of this report:	
Independent Auditors' Report	34
Balance Sheets - December 31, 1995 and 1994	
Statements of Operations - Years Ended December 31, 1995, 1994 and 1993	36

Statements of Stockholders' Equity - Years Ended December 31, 1995, 1994 and 1993

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Statements of Cash Flows - Years Ended December 31, 1995, 1994 and 1993  $\,$ 

Notes to Financial Statements

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- 2. Financial Statement Schedule.
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- 3. Exhibits.
- 4. Exhibit Number

2.1 Amended and Restated Agreement of Merger and Plan of Reorganizatin 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 Chemex Form 8-B dated July 12, 1989, Commission File Number 9-9134)
- 3.2 Bylaws (Incorporated by referenced to Exhibit 3(b) of the Chemex Form 8-B dated July 12, 1989, Commission File Number 0-9314)
- 3.3 Certificate of Amendment of Certificate of Incorporation filed August 21, 1992.51
- 3.4 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)

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Exhibit Number Page

- 3.5 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)
- 10.0 Material contracts:
- 10.1 Employee Stock Ownership Plan (Incorporated by the reference to Exhibit 10 of the Company's Form 10-K for the year ended December 31, 1986, commission File Number 0-9314)
- 10.2 Employee Stock Ownership Trust (Incorporated by reference to Exhibit 10 of the Company's form 10-K for the year ended December 31, 1986, commission File Number 0-9314)
- 10.3(a) Employment Agreement of Mr. Herbert H. McDade, Jr. (Incorporated by reference to Exhibit 10 of the Company's Form 10-K for the year ended December 31, 1988,

- Commission File Number 0-9314)
- 10.3(b) First Amendment to Employment Agreement of Mr. Herbert H. McDade, Jr. Dated July 31, 1989 (Incorporated by reference to Exhibit 10.5(b) of the Company's Form S-1 dated November 7, 1989, Commission File Number 33-30685)
- \* 10.3(c) Second Amendment to Employment Agreement of Mr. Herbert H. McDade, Jr. dated December 13, 1989 (Incorporated by reference to Exhibit 10.3(a) of the Company's form 10-K for the year ended December 31, 1990)
- \* 10.3(d) Third Amendment to Employment Agreement of Mr. Herbert H. McDade, Jr. dated July 11, 1990 (Incorporated by reference to Exhibit 10.3(a) of the Company's Form 10-K for the year ended December 31, 1990)
- \* 10.3(e) Fourth Amendment to Employment Agreement of Mr. Herbert H. McDade, Jr. dated June 25, 1991 (Incorporated by reference to Exhibit 10 of the Company's Form 10-K for the year ended December 31, 1991)
- 10.3(f) Fifth Amendment to Employment Agreement of Mr. Herbert H. McDade, Jr. Dated December 31, 1991 (Incorporated by reference to Exhibit 6 of the Company's Form 10-O for the quarter ended June 30, 1994)
- \* 10.3(g) Sixth Amendment to Employment Agreement of Mr. Herbert H. McDade, Jr. dated April 29, 1994 (Incorporated by reference to Exhibit 6 of the Company's Form 10-Q for the quarter ended June 30, 1994)
  - 10.4 Joint Venture and General Partnership Agreement between Block Drug Company and Chemex Pharmaceuticals, Inc., dated June 20, 1990, (Incorporated by reference to Exhibit 28.1 of the Company's Form S-3 dated August 5, 1991, Commission File Number 33-42052)

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Exhibit Number

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- 10.5 Products Development Agreement between Block/Chemex, G.P. and Chemex Pharmaceuticals, Inc. dated June 20, 1991, Incorporated by reference to Exhibit 28.2 of the Company's Form S-3 dated August 5, 1991, Commission File Number 33-42052)
- 10.6 Patent Purchase Agreement between Block Drug Company, Inc. and ACCESS Pharmaceuticals, Inc. dated June 20, 1992, (Incorporated by reference to Exhibit 28.2 of the Company's Form S-3 dated August 5, 1991, Commission File Number 33-42052)
- 10.7 Irrevocable Assignment of Proprietary Information with Dr. Charles G. Smith (Incorporated by reference to Exhibit 10.6 of the ACCESS Form 10-K for the year ended December 31, 1991)
- 10.8 Option Agreement with Mr. Vernon Taylor III dated September 25, 1990 (Incorporated by reference to Exhibit 10 of the Company's Form 10-K for the year ended December 31, 1990)
  - 10.9 Conversion Agreement with Sentinel Charitable Remainder Trust dated June 18, 1990 (Incorporated by reference to Exhibit 10 of the Company's Form 10-K for the year ended December 31, 1990)
  - 10.10 Advisory Agreement with D. Blech & Company, Inc. dated November 8, 1990 (Incorporated by reference to Exhibit 10 of the Company's Form 10-K for the year ended December 31, 1990)
  - 10.11 Asset Purchase Agreement with Block Drug Company dated June 29, 1990 (Incorporated by reference to Exhibit 10 of the Company's Form 10-K for the year ended December 31, 1990)
  - 10.12 Assignment by Block Drug to Joint Venture of Block/Penederm, Inc. Agreement dated March 24, 1993 (Incorporated by reference to Exhibit 10 of the Company's Form 10-K for the year ended December 31, 1993)
  - 10.13 Sale of 10% interest in the Block/Chemex Joint Venture by Chemex Pharmaceuticals, Inc. to the Block Drug Company, Inc. (Incorporated by reference to Exhibit 6 of the Chemex Form 10-Q for the quarter ended June 30, 1994)
  - 10.14 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)
  - 10.15 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)
  - 10.16 Patent Purchase Agreement dated April 5, 1994 between

David F. Ranney and ACCESS Pharmuceuticals, Inc.

10.17 First Amendment to Patent Purchase Agreement dated
January 23, 1996 between David F. Ranney and ACCESS
Pharmaceuticals, Inc. 67

23.0 Consent of experts and counsel

23.1 Consent of Independent Auditors

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\* 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.

</TABLE>

There were no reports on 8-K during the fourth quarter of 1995.

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## SIGNATURES

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

### ACCESS PHARMACEUTICALS, INC.

Date March 29, 1996 By /s/ Kerry P. Gray

\_\_\_\_\_\_

Kerry P. Gray President and Chief Executive

Officer, Treasurer

Date March 29, 1996

By /s/ Stephen B. Thompson

Stephen B. Thompson Chief Financial Officer

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, 1996 By /s/ Kerry P. Gray

Kerry P. Gray

President and Chief Executive

Officer, Treasurer

Date March 29, 1996 By /s/ Herbert H. McDade, Jr.

Herbert H. McDade, Jr., Director

Date March 29, 1996 By /s/ David F. Ranney

David F. Ranney, Director

Date March 29, 1996 By /s/ J. Michael Flinn

J. Michael Flinn, Director

J. Michael Filmi, Director

Date March 29, 1996 By /s/ Elizabeth M. Greetham

Elizabeth M. Greetham, Director

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Independent Auditors' Report

The Board of Directors and Stockholders ACCESS Pharmaceuticals, Inc.:

We have audited the financial statements of ACCESS Pharmaceuticals, Inc. (formerly Chemex Pharmaceuticals, Inc.) as of December 31, 1995 and 1994, and the related statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 1995. 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 financial position of ACCESS Pharmaceuticals, Inc., as of December 31, 1995 and 1994, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 1995, in conformity with generally accepted accounting principles.

KPMG Peat Marwick LLP

Dallas, Texas March 29, 1996

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#### ACCESS PHARMACEUTICALS, INC.

#### Balance Sheets

<TABLE> <CAPTION>

Assets	December 31, 1995 December 31, 1994				
<\$>	<c></c>	<c:< td=""><td>&gt;</td></c:<>	>		
Current Assets: Cash and cash equivalents (Note 1) Accounts receivable (Note 1) Loan to API (Note 6) Prepaid expenses and other assets	1	48,000 00,000	\$1,335,000 136,000  0 151,000		
Total current assets	-	9,000	1,622,000		
Furniture and Equipment at cost Less accumulated depreciation		62,00	123,000 (61,000)		
Other Assets			20,000		
Total Assets	\$2,129	*	\$1,704,000 ======		

## Liabilities and Stockholders' Equity

Current Liabilities

Accounts payable \$136,000 \$190,000 Accrued lease settlement (Note 5) 30,000 Financed insurance premium 73,000 90,000 Accrued merger closing expenses (Note 9) 140,000 Other accrued liabilities 57,000 85,000 Total current liabilities 436,000 365,000 Long-term liabilities 12,000 7,000 Total liabilities 443,000 377,000

Commitments (Note 5)

Stockholders' Equity (Notes 2 and 3) Preferred stock, \$.01 par value. Authorized 5,000,000 shares; none issued or outstanding Common stock, \$.04 par value. Authorized 22,000,000 shares; outstanding 8,737,788 and 8,678,660 shares 350,000 347,000 40,367,000 40,352,000 Additional paid-in capital (5,000) Treasury stock, 1,677 shares (5,000) (39,026,000) (39,367,000) Deficit Total Stockholders' Equity 1,686,000 1,327,000 Total Liabilities and Stockholder's Equity \$2,129,000 \$1,704,000 </TABLE> See accompanying notes to financial statements. 34

## ACCESS PHARMACEUTICALS, INC

#### Statements of Operations

<table> <caption></caption></table>				
	Year	rs ended Decer	mber 31,	
		1994		
<s> Revenues:</s>		<c></c>		
Sale of proprietary rights (Note 8) Joint Venture project revenue (Note	8)	\$2,500,000	\$1,700,000 1,371,000	- \$1,468,000
Amlexanox project revenue Actinex royalty (Note 7) Interest and dividend income		1,000 54,000	1,371,000 - 26,000 - 65,000	- 9,000 139,000
-	2,945,000	3,162,000	1,656,000	)
Expenses: Research and Development (Notes 2 Amlexanox/Joint Venture (Note 8) ACCESS proprietary General, Administrative and Other: Operating expenses Professional fees-related parties (Note Amortization of stock awards (Note Settlement of litigation	1,3 ote 6)	587,000 666,000 341,000 1 13,000 (3,000)	2,438,000 153,000 ,381,000 1 27,000 122,000 475,000 	324,000 ,895,000 108,000 (161,000)
Income (loss) before income taxes Provision for income taxes (Note 4)		341,000	(959,000)	
Net income (loss)	\$34	41,000 (\$9	959,000) (\$3	,567,000)
Net income (loss) per common share (	Note 1)	\$0.0	04 (\$0.11	
Average number of common and equi common shares outstanding (Note 1	valent)	8,717,402 === ====	2 8,543,003	8,384,904

  |  |  |  ||  |  |  |  |  |
See accompanying notes to financial statements

# STATEMENTS OF STOCKHOLDERS' EQUITY Years Ended December 31, 1995, 1994, 1993

# <TABLE> <CAPTION>

SS		ommon ares		ock ount	Add'l. Paid-in Capital	Deficit	Treasu	Total 1ry Stockhold ck Equity	ers'	
[Note 3(c)]	-	C>	-	>	<c></c>	-	-	-	(\$5,000)	\$5,525,0
Note 3(a) and 3(b)] 66,750 2,000 20,000 22,000 (161,000) Stock award amortization [Note 3(d)] (161,000) (1	Note 3(c)]		63	5,000	156,0	00		161,000		
[Note 2(a)] 25,000 1,000 49,000 50,000 [3,567,000] Net loss - 1993 8,524,076 \$341,000 \$40,102,000 (\$38,408,000) (\$5,000) \$2,00  [Suance of common stock for ESOP [Note 3(c)] 154,580 6,000 95,000 101,000 [55,000] Warrants exercised 4 0 0 [959,000] Balances at December 31, 1994 8,678,660 \$347,000 \$40,352,000 (\$39,367,000) (\$5,000) \$1,32  [Suance of common stock for ESOP [Note 3(d)] 155,000 155,000 [959,000]  [Stock/SARs award expense [Note 3(d)] 155,000 [959,000] [959,000]  [Balances at December 31, 1994 8,678,660 \$347,000 \$40,352,000 (\$39,367,000) (\$5,000) \$1,32  [Suance of common stock for ESOP [Note 3(a) and 3(b)] 14,803 1,000 (4,000) (3,000) [3,000] Net income - 1995 341,000 341,000	[Note 3(a) and 3(b)] Stock award amortization [Note 1	3(d)]	6,750	2,0		,		,		
Balances at December 31, 1993 8,524,076 \$341,000 \$40,102,000 (\$38,408,000) (\$5,000) \$2,000  [Issuance of common stock for ESOP [Note 3(c)] 154,580 6,000 95,000 101,000  Stock/SARs award expense [Note 3(d)] 155,000 155,000  Warrants exercised 4 0  (959,000) (959,000)  Balances at December 31, 1994 8,678,660 \$347,000 \$40,352,000 (\$39,367,000) (\$5,000) \$1,300  Issuance of common stock for ESOP [Note 3(c)] 44,325 2,000 19,000 21,000  Issuance of stock on exercise of SARs [Note 3(a) and 3(b)] 14,803 1,000 (4,000) (3,000)  Net income - 1995 341,000 341,000	[Note 2(a)] Net loss - 1993	25,00		,	(3,	567,000)		(3,567,000)		
Issuance of common stock for ESOP [Note 3(c)]	Balances at December 31, 1993								(\$5,000)	\$2,030,0
issuance of common stock for ESOP [Note 3(c)] 44,325 2,000 19,000 21,000 [ssuance of stock on exercise of SARs [Note 3(a) and 3(b)] 14,803 1,000 (4,000) (3,000) [Note income - 1995 341,000 341,000	[Note 3(c)] Stock/SARs award expense [Not Warrants exercised Net loss - 1994	154,5 e 3(d)]		6,000		155,000		0	5,000	
[Note 3(c)] 44,325 2,000 19,000 21,000 Issuance of stock on exercise of SARs [Note 3(a) and 3(b)] 14,803 1,000 (4,000) (3,000) Net income - 1995 341,000 341,000	Balances at December 31, 1994		8,67	8,660	\$347,000	\$40,3	52,000	(\$39,367,000)	(\$5,000)	\$1,327,0
Balances at December 31, 1995 8,737,788 \$350,000 \$40,367,000 (\$39,026,000) (\$5,000) \$1,60	[Note 3(c)] Issuance of stock on exercise of [Note 3(a) and 3(b)]	44,32 SARs		,	.,	000)		(3,000	))	
	Balances at December 31, 1995		8,73	7,788	\$350,000	\$40,3	67,000	(\$39,026,000)	(\$5,000)	\$1,686,0

  |  |  |  |  |  |  |  |  |See accompanying notes for financial statements

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## ACCESS PHARMACEUTICALS, INC

## Statements of Cash Flows

<TABLE> <CAPTION>

	Ye	ars ended	December 31,		
	1995	1994	1993	- <del></del>	
<\$>	<c></c>	<c></c>	· <c></c>	· <b></b>	
Cash Flows from Operating Activities:					
Net income (loss)	\$34	1,000	(\$959,000)	(\$3,567,000)	
Adjustments to reconcile net income (loss)					
to cash provided by (used by) operating ac	tivities:				
Depreciation	15,0	000	25,000	24,000	
Common stock issued in payment for service				50,000	
Common stock contributed to Employee Sto	ck Owners	nip Plan	20,00	0 101,000	161,000
Stock award amortization		(3,000)	155,000	(161,000)	
Change in assets and liabilities:					
Accounts receivable	1.		217,000		
Prepaid expenses and other assets		78,000	43,00	00 (78,000)	
Accounts payable	(5	4,000)	(94,000)	(35,000)	
Accrued taxes		-	- (431,0	000)	
Accrued lease settlement		30,000		-	
Accrued litigation settlement		-	(475,000)		
Accrued merger closing expenses		140,0	00 -		
Other accrued liabilities	(4	15,000)	(36,000)	(48,000)	
Net cash provided by (used by) operating	g activities	 s 6	558,000 (	1,023,000) (3,	712,000)

Cash Flows from Investing Activities: Capital expenditures	-	-	(3,000)	
Net cash used by investing activities			(3,000)	
Loan to API	(5,0)	- 000) (4	- 22,000 4,000) (5,0	) 000)
Net cash provided by (used by) financing acti		(105,000)	(4,000)	17,000
Net increase (decrease) in cash and cash equivalent	s 			(\$3,698,000)
Cash and cash equivalents at beginning of period		1,335,000	2,362,000	6,060,000
Cash and cash equivalents at end of period			\$1,335,000	
Cash paid for interest Cash paid for income taxes	\$6,174	\$5,233	\$3,300 \$431,000	

  |  |  |  || See accompanying notes to financial statements |  |  |  |  |
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# ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements

(1) The Company and Summary of Significant Accounting Policies

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## (a) The Company

ACCESS Pharmaceuticals, Inc. ("ACCESS" or the "Company"), formerly known as Chemex Pharmaceuticals, Inc. ("Chemex"), is engaged in research and development activities with a broad platform technology for enhancing the site targeting of intravenous therapeutic drugs, MRI contrast agents and radiopharmaceutical diagnostic and therapeutic agents. The ACCESS technology is based on natural carbohydrate carriers.

Chemex merged with ACCESS Pharmaceuticals, Inc. ("API") on January 25, 1996 and in March 1996 concluded a \$6 million private placement of 8.57 million shares of common stock. On January 25, 1996, Chemex changed its name to ACCESS (see note 9).

Prior to the merger, the Company was engaged in research and development activities for certain dermatological products relating to the determination of the potential use, if any, of elements of certain natural product and synthetic compounds for therapeutic purposes. To commercialize these activities, a joint venture, (the "Joint Venture") was signed with Block Drug Company, Inc. ("Block") in June 1991 and represented the commencement of planned operations. The Joint Venture was dissolved effective December 31, 1994, and pursuant to such dissolution, the original compounds that had been contributed to the Joint Venture by the Company were returned to the Company, with the exception of Amlexanox. The Company transferred its rights to Amlexanox to Block for a non-refundable upfront royalty payment of \$2.5 million plus future royalties, with the consent of Takeda Chemicals (the licensor) and approval of Chemex shareholders on September 14, 1995 (see Note 8).

The Company's products will require clinical trials, FDA approval 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 does the Company.

#### (b) Cash and Cash Equivalents

-----

The Company considers all highly liquid debt instruments with an original maturity of three months or less to be cash equivalents for purposes of the statements of cash flows.

#### (c) Depreciation

-----

Depreciation of furniture and equipment was provided using the straight-line method based on estimated useful lives of 5 years. Depreciation expense for the years ended December 31, 1995, 1994 and 1993, amounted to \$15,000, \$25,000 and \$24,000, respectively. In connection with the merger, the Company sold the remainder of its fixed assets to API at book value in the fourth quarter of 1995.

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ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

### (d) Net Income (Loss) Per Common Share

\_\_\_\_\_

Net income (loss) per common share is calculated based upon the weighted average number of common shares and common equivalent shares outstanding during the years ended December 31, 1995, 1994 and 1993 of 8,717,402, 8,543,003 and 8,384,904, respectively. In 1995, 1994 and 1993 any common equivalent shares were either not material or anti-dilutive.

#### (e) Revenues

-----

The Company entered into three separate agreements with Block under which it performed contract research and development. The first agreement represented the sale of Actinex(R) to Block, whereby the Company was reimbursed for any outside costs it incurred in connection with the further development of Actinex(R). The second agreement with Block was the Joint Venture, under which the Company was responsible for performing all research and development of the Joint Venture products. Through December 31, 1994 (the effective date of the dissolution of the Joint Venture), the Company shared equally with Block all research and development expenses, after the first \$3 million of expenditures which was paid by Block, however, this agreement was terminated by mutual consent on December 31, 1994 (see note 8 for further discussion). On June 7, 1995, the Company entered into the third agreement with Block to sell its rights to Amlexanox for a non-refundable upfront royalty payment of \$2.5 million plus future royalties, if any, which was approved by the Company's shareholders on September 14, 1995. Until the completion of the agreement, 50% of research conducted for Amlexanox was paid for by Block.

#### (f) Research and Development Expenses

-----

All costs of research and development are expensed in the period incurred.

#### (g) Accounts Receivable

-----

Accounts receivable as of December 31, 1995 and December 31, 1994 were \$48,000 and \$136,000, respectively, and in 1995 was due from API in connection with the sale of the Company's furniture and computer equipment and in 1994 were entirely due from Block for the Joint Venture research and development expenses and Actinex(R) royalty.

#### (h) Use of Estimates

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Management of the Company has made a number of estimates and assumptions relative to the reporting of assets and liabilities to prepare these financial statements in conformity with generally accepted accounting principles.

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#### ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

#### (2) Stockholders' Equity

-----

#### (a) Common Stock

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From time to time, the Company has issued restricted shares of its common stock as payment for various costs and services. These shares were valued by the Company's Board of Directors (the Board) based upon the quoted market price on the date of issue, discounted as considered appropriate by the Board, for the restricted nature of the stock. During the years ended December 31, 1995 and 1994, the Company did not issue any shares of common stock as payment for any obligations. During the year ended December 31, 1993, the Company issued 25,000 shares at a value of \$50,000 as payment of outside investment banking services.

#### (b) Warrants

-----

The Company has authorized the issuance of up to 500,000 Units, consisting in the aggregate of 500,000 shares of Common Stock and warrants exercisable in the aggregate for 700,000 shares of Common Stock. The authorization of the Units was made in connection with a Conversion Agreement, dated June 18, 1990, by and between ACCESS and Sentinel Charitable Remainder Trust (the "Conversion Agreement"). Pursuant to the terms of the Conversion Agreement, each Unit has an exercise price of \$2.50 and the rights of Sentinel Charitable Remainder Trust to subscribe for the Units were to expire on July 31, 1996. This Conversion Agreement was amended as of December 14, 1995 by the Letter Agreement to provide that the right of Sentinel Charitable Remainder Trust to subscribe for the Units now expire on January 1, 1999.

Each warrant issuable in connection with the Units described above is exercisable for one share of Common Stock (subject to adjustment as provided in the warrant), with 500,000 of the warrants excisable at \$6.25 and the remaining 200,000 warrants exercisable at \$2.50, all upon the terms and conditions set forth in the Conversion Agreement. The warrants expire on January 1, 2000.

Under the terms of merger on January 25, 1996, a maximum of 750,000 warrants exercisable at \$0.75 per share with a 5 year expiration from the date of issue, may be issued to the former holders of record of API Common Stock upon the occurrence of certain conditions.

#### (3) Stock Option Plan and Employee Stock Ownership Plan

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#### (a) Stock Option Plan

-----

The Company adopted a stock option plan (the "1987 Stock Awards Plan") and reserved 1,725,000 shares of the Company's common stock for issuance to optionees including officers,

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ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

employees, and other individuals performing services for the Company. The 1987 StockAwards Plan replaced the previously approved Restated Non-Qualified Stock Option Plan (the "Restated Plan") and includes stock appreciation rights, which

vested based on the achievement of certain financial and operational benchmarks. Options granted under the plans were generally exercisable over a ten-year period from the date of grant, however, as a result of certain events occurring in 1995, all issued options became vested and exercisable. The shareholders replaced the 1987 Plan on January 25, 1996 with the 1995 Stock Option Plan. No further grants have been or can be made under the 1987 Plan.

Under the 1995 Stock Option Plan, 2,000,000 shares of ACCESS Common Stock are reserved for issuance to employees, officers, directors and consultants at the Company.

Summarized information for the 1987 Plan is as follows:

<TABLE> <CAPTION>

	1987 Plan			
	Incentive Stock Options	SARs(1)		
<s></s>		 <c></c>		
Outstanding options at December 31, 1994	.0.	,602 360,161		
Granted	0	0		
Forfeited	(116,505)	(6,693)		
Exercised	. , ,	(14,803)		
Outstanding options				
at December 31, 1995	976,	338,665		
At December 31, 1995: o Average exercise price o	f			
outstanding options	\$2.42	\$0.00		
o Exercisable options	976,0	97 338,665		

</TABLE>

(1) See Note [3(d)]

## Non-employee Director Stock Option Plan

The Company adopted the Non-Employee Director Stock Option Plan during 1987 and reserved 467,500 shares of the Company's common stock for options awarded under the plan. Directors who had options in the Restated Plan relinquished those options for equivalent options in the Non-Employee Director Stock Option Plan. During 1995, there were no options granted by the Company. Shares under option at December 31, 1995 are as follows:

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ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

## 1987 Non-Employee Director Plan

Outstanding options at December 31, 1994 299,054 Granted 0 (19,937) Forfeited Exercised 0 Outstanding options at December 31, 1995 279,117

At December 31, 1995

o Average exercise price of outstanding options

\$2.90 o Exercisable options 279,117 Both of the Plans described in (a) and (b) above provide for shares to be purchased for cash or with shares of the Company's common stock owned by the optionee with a market value equal to the aggregate option price.

Stock options and stock appreciation rights vest to the optionees immediately upon a change in control of the Company. Change in control is generally defined as the acquisition of 25% or more of the common stock of the Company by an individual or a group. Change in control did occur at the date of the merger, January 25, 1996, and as a result, all unvested options vested.

## (c) Employee Stock Ownership Plan ("ESOP")

-----

Effective January 1, 1986, the Company adopted a qualified Employee Stock Ownership Plan (ESOP) in which all employees are eligible to participate. The ESOP provides that the Company may elect to match employee contributions at varying percentage rates designated by the Company (50% in 1993, 1994, and 1995) and may make an annual contribution to the ESOP as determined by the Board, with a maximum contribution not to exceed the amount deductible under the Internal Revenue Code. Contributions to the ESOP can be made in cash, mutual funds or in common stock of the Company. During the years ended December 31, 1995, 1994 and 1993, the Company contibuted 41,427, 151,608 and 116,202 shares of common stock to the ESOP valued at \$18,460, \$98,006 and \$158,064, respectively. Employee contributions to the ESOP during the year ended December 31, 1993 totalled \$71,645, of which \$2,744 was used to purchase 1,561 shares and \$68,901 was invested in mutual funds; during the year ended December 31, 1994, contributions totalled \$73,222 of which \$2,535 was used to purchase 2,972 shares, and \$70,687 was invested in mutual funds; and during the year ended December 31, 1995, contributions totalled \$36,921 of which \$1,354 was used to purchase 2,898 shares and \$35,567 was invested in mutual funds. The Company intends to terminate the Plan and no Company contributions are anticipated in 1996.

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#### ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

#### (d) Stock Award Amortization/Cancellation

\_\_\_\_\_

The Company amortizes stock award compensation expense for the difference between the issuance or exercise price of stock options granted and the fair market value of the common stock on the date of the grant, over the period benefitted. SARs are treated in the same manner, however, for SARs that were payable in cash, a further amortization expense (or credit to expense) was recorded for the difference between the fair market value of the common stock at the current period end and the fair market value on the grant date or the last fiscal period, whichever is later. In addition, forfeited stock options for employees that terminate from the Company prior to full vesting of their stock options are recorded as a reduction to stock awards expense, representing the original difference between fair market value of the common stock and the exercise price of the stock option on the grant date, for any forfeited unvested options.

In 1992, the Board of Directors passed a resolution that no SARs were to be paid in cash. During 1993, 50,000 SARs were exercised. The difference between the fair market value of the stock as originally recorded and the market value as of the date the SARs were exercised was recorded as a reduction of stock award amortization of \$161,000. In 1994, bonuses were paid to employees in the form of SARs totalling 35,210 options. In addition, 223,829 SARs were awarded to the three former corporate officers contingent on operational milestones. The difference between the fair market value of the SARs as of the date of the grant and the zero exercise price was recorded as stock award expense of \$122,000 in 1994. In 1995, no SARs were awarded. In 1995, the difference between the fair market value of the stock as originally recorded and the market value as of the date the SARs were exercised was

recorded as a reduction of stock award amortization expense of \$3,000.

#### (4) Income Taxes

-----

The Company follows Statement of Financial Accounting Standards Number 109 - Accounting for Income Taxes ("FASB 109"). No provision for federal income taxes has been made since inception due to the operating losses incurred for income tax purposes. At December 31, 1995, 1994 and 1993, the Company had deferred tax assets primarily comprised of the tax benefits of net operating loss carry-forwards and temporary differences relating to compensation expense. Because the Company has a history of losses, a 100% provision against the deferred tax assets was recorded. At December 31, 1995, the Company's regular and alternative minimum tax net operating loss carry-forwards for federal income tax purposes approximate \$34 million, which, if not utilized, will expire in varying amounts through the year 2009. However, as a result of the merger on January 25, 1996, (see note 9), a change in control occurred for federal income tax purposes which limited the utilization of net operating loss carry-forwards to approximately \$530,000 per year.

#### (5) Commitments

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

Rent expense was \$217,551, \$201,552 and \$202,028 for the years ended December 31, 1995, 1994 and 1993 respectively. Effective as of November 2, 1995 the Company terminated its lease agreement for

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#### ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

its former principal office space in Fort Lee, New Jersey. Pursuant to the settlement agreement, approximately \$79,000 in consideration of the termination of the lease has been expensed of which \$30,000 remains as an accrual at December 31, 1995. Limited temporary office space was leased in Tarrytown, New York, until the merger.

Effective January 25, 1996 the Company relocated to API's corporate offices in Dallas, Texas. API's office lease annual minimum rental for 1996 is approximately \$58,767 and for 1997 is approximately \$17,046.

#### (6) Related Party Transactions

-----

The following is a table of related party transactions for the years ended December 31, 1995, 1994 and 1993.

# <TABLE> <CAPTION>

	Year ended December 31,				
-	1995	1994	1993		
<s> Legal fees-Company's forme</s>	<c></c>	<c></c>	<c></c>		
firm of which a Partner was a Director	also a		\$44,228		
Consulting fees-Director		\$13,000	\$26,950	54,132	
Consulting fees-Director			10,000		

## </TABLE>

An attorney for the Company's former law firm was, and two consultants were members of the Company's Board of Directors. As of July 29, 1993, the attorney did not stand for reelection to the Board and his law firm is no longer retained by the Company.

Pursuant to the terms of the merger agreement, the Company was obligated to loan, at any time prior to the closing of the transaction, an aggregate amount of up to \$250,000 to API, upon request of API. On October 4, 1995, the Company made a loan to API of

## (7) Sale of Actinex(R) Technology

-----

On June 29, 1990, the Company signed a definitive agreement to sell Actinex(R), a product developed by the Company for the treatment and prevention of actinic keratoses to Block. As of December 31, 1990, the Company received a total of \$2 million in non-refundable payments from Block for the sale of Actinex(R). The Company received from Block during fiscal 1992 the following additional milestone payments: \$1 million upon receipt of the "approvable" letter from the FDA, \$3 million upon receipt of the "approval" letter from the FDA, \$2 million upon first sale of the product by Block. An additional milestone of \$2 million to be paid on the first two anniversaries of the first sale was waived since the FDA did not grant the approval of the drug by June 29, 1992. In its place, Block has agreed

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#### ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

to pay a 2.5% royalty on the fist \$40 million of cumulative sales of Actinex(R) (equivalent to \$1 million). The Company is also entitled to receive royalties on the sale of the product worldwide (5% on sales in countries where the patent is protected and 2.5% on sales in countries where the patent is not protected) after the first \$40 million of cumulative sales are achieved. The Company recorded royalties of \$1,000 in 1995, \$26,000 in 1994 and \$49,000 in 1993.

#### (8) Block Joint Venture and Subsequent Dissolution

-----

On June 20, 1991 the Company and Block entered into a Joint Venture and for such purpose established an equally-owned New Jersey general partnership. The objective of the Joint Venture was to develop, manufacture and market products developed by the Joint Venture. Both Companies were to share equally in the profits of the Joint Venture.

The Company contributed all of its dermatological products to the Joint Venture and agreed to dedicate its current research staff to the performance of the Joint Venture research and development of up to \$17 million during the five years of the research and development agreement. The initial \$3 million of research and development funding was paid for by Block after which each partner was obligated to contribute 50% of research and development cost up to an aggregate of \$14 million. Each party was obligated to offer all of their respective new dermatological products to the Joint Venture during the five year period. In addition, under the terms of the agreement, Block paid the Company \$2 million for certain of its proprietary assets and Block contributed such assets to the Joint Venture.

As a result of entering into the Joint Venture, the Company's research and development staff activities were then directed almost exclusively to the Joint Venture effort. The Joint Venture was developing Amlexanox (aphthous ulcers), EPC-K (inflammation of the skin), CHX-100 (anti-wrinkling), and CHX-108 (mild/moderate psoriasis).

In June 1994, Block purchased an additional 10% of the Joint Venture from the Company (20% of the Company's share) for \$1,700,000, thereby changing the Joint Venture ownership to a 60/40 split in favor of Block. The Company retained the right to re-purchase the 10% interest for up to eighteen months after the purchase by Block.

As of December 31, 1994, by mutual consent, Block and the Company agreed to terminate the Joint Venture. As part of the dissolution, the Company returned to Block for \$1,700,000, the 10% Joint Venture ownership purchased by Block in June 1994 in return for the sale of certain proprietary rights for Amlexanox to Block for a like amount; Block returned its 50% share of all of the Joint Venture dermatology drug portfolio (except Amlexanox); the Company returned its ownership share of Penderm's Acticin to Block; and Block and the Company entered into separate joint ownership agreements for Amlexanox.

Block and the Company have concluded several agreements as part of the Joint Venture dissolution: (1) Asset Distribution Agreement ("ADA") which effectively dissolves the Joint Venture and specifies the distribution of assets of the Joint Venture; (2) Product Development Agreement ("PDA") and Manufacturing, Marketing and Distribution Agreement ("MMS") which established the joint ownership

#### ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

of Amlexanox and the responsibilities of each party; and (3) a separate agreement giving the Company an option to transfer its share of the ownership rights to Amlexanox to Block for a non-refundable upfront royalty payment plus future royalties, subject to consent by Takeda Chemicals (the licensor of Amlexanox) and the Company shareholder approval.

The ADA distributes the following rights to products: the Company received Block's share of the rights to EPC-K1 a drug under license from Senju Pharmaceuticals for atopic dermatitis; CEDE-108-potentially for psoriasis; and CHX-100 for the treatment of photoaging of the skin; and Block received the Company's share to the rights for Penederm's retinoic acid product.

The PDA and MMS Agreements outline the responsibilities of the parties in terms of the development and commercialization of any Amlexanox product for all oral use. The Company was responsible for all development and regulatory activities and Block was responsible for manufacturing, marketing and distribution of any Amlexanox products. The MMS Agreement also defines the sharing of any profits or losses of any Amlexanox product and further allows the Company the option, on a country by country basis, to agree to a profit and loss arrangement or a royalty.

On June 7, 1995, the Company entered into an agreement with Block to sell its rights to Amlexanox for a non-refundable upfront royalty payment of \$2.5 million plus future royalties, if any, which was approved by the Company shareholders on September 14, 1995.

## (9) Subsequent Events

-----

On January 25, 1996, the Company's Shareholders, at a Special Shareholders Meeting, approved the merger with API. Under the terms of the 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 13,919,979 shares of registered common stock of Chemex. 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. As of December 31, 1995, the Company accrued \$140,000 for estimated costs to complete the merger.

As a result of the merger, the former API Stockholders own 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 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," Chemex remains the continuing legal entity and registrant for Securities and Exchange Commission reporting purposes.

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ACCESS PHARMACEUTICALS, INC. Notes to Financial Statements (continued)

The following summarizes API's results of operations for the years indicated:

Revenues \$845,000 \$1,048,000

------

Research and development
Other Expenses 7
Depreciation 12

675,000 714,000 752,000 695,000 121,000 115,000 1,548,000 1,524,000 -------Net loss (\$703,000) (\$476,000)

In March 1996 the Company concluded a \$6 million Private Placement of 8.57 million shares of common stock. The cash infusion will be used to continue the advancement of the product portfolio which focuses on increasing the therapeutic benefit and improving the efficiency of oncology therapeutics and diagnostic agents by selectively targeting sites of disease and accelerating drug clearance. The shares issued in the private placement have not been registered, however the company has agreed to file a registration statement within 90 days of the issuance covering such shares. The investors have agreed not to sell any of the shares purchased in the offering until 180 days after the closing.

As of January 29, 1996, ACCESS retained Mr. David Blech, the income beneficiary of the Sentinel Charitable Remainder Trust (see Note 2(b)), as a consultant to the Company for one year to advise on structuring transactions including equity placements, licensing agreements and research and development collaborations. Under the terms of the agreement Mr. Blech was paid \$480,000 in 1996 and received immediately exercisable warrants to purchase 600,000 shares of Common Stock at an exercise price of \$1.00 per share, which warrants expire in the year 2000.

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CERTIFICATE OF AMENDMENT OF CERTIFICATE OF INCORPORATION

CHEMEX PHARMACEUTICALS, INC., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware,

#### DOES HEREBY CERTIFY:

FIRST: That a meeting of the Board of Directors of Chemex Pharmaceuticals, Inc. resolutions were duly adopted setting forth a proposed amendment of the Certificate of Incorporation of said corporation, declaring said amendment to be advisable and calling a meeting of the stockholders of said corporation for consideration thereof. The resolution setting forth the proposed amendment is as follows:

"RESOLVED, that Article V, Section A of the Certificate of Incorporation of this corporation be amended by deleting said Article V, Section A in its entirety and substituting the following therefor:

'A. The aggregate number of shares of common stock which the Corporation shall have authority to issue is twenty-two million (22,000,000) shares with a par value of four cents (\$0.04) per share."

SECOND: That thereafter, pursuant to the resolution of its Board of Directors, a meeting of the stockholders of said corporation was duly called and held, upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware at which meeting the necessary number of shares as required by statute were voted in favor of the amendment.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

FOURTH: That the capital of said corporation shall not be reduced under or by reason of said amendment.

IN WITNESS WHEREOF, said Chemex Pharmaceuticals, Inc. has caused this certificate to be signed by Herbert H. McDade, Jr., its President, Ralph L. Poucher, its Secretary, this 13th day of August, 1992.

BY: /s/Herbert H. McDade, Jr.

Herbert H. McDade, Jr.

ATTEST: /s/Ralph L. Poucher
-----Ralph L. Poucher

# CERTIFICATE OF AMENDMENT OF CERTIFICATE OF INCORPORATION

CHEMEX PHARMACEUTICALS, INC., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware,

#### DOES HEREBY CERTIFY:

FIRST: That at a meeting of the Board of Directors of Chemex Pharmaceuticals, Inc., resolutions were duly adopted setting forth a proposed amendment of the Certificate of Incorporation of said corporation, declaring said amendment to be advisable and calling a meeting of the stockholders of said corporation for consideration thereof. The resolution setting forth the proposed amendment is as follows:

"RESOLVED, that Article V, Section A of the Certificate of Incorporation of this corporation be amended by deleting said Article V, Section A in its entirety and substituting the following therefor:

'A. The aggregate number of shares of common stock which the Corporation shall have authority to issue is twenty-two million (22,000,000) shares with a par value of four cents (\$0.04) per share."

SECOND: That thereafter, pursuant to the resolution of its Board of Directors, a meeting of the stockholders of said corporation was duly called and held, upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware at which meeting the necessary number of shares as required by statute were voted in favor of the amendment.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

-2-

FOURTH: That the capital of said corporation shall not be reduced under or by reason of said amendment.

IN WITNESS WHEREOF, said Chemex Pharmaceuticals, Inc. has caused this certificate to be signed by Herbert H. McDade, Jr., its President, and Ralph L. Poucher, its Secretary, this 13th day of August, 1992.

BY: /s/ Herbert H. McDade, Jr.

Herbert H. McDade, Jr.

ATTEST: /s/ Ralph L. Poucher
Ralph L. Poucher

#### PATENT PURCHASE AGREEMENT

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THIS PATENT PURCHASE AGREEMENT (the "Agreement") is made and entered into as of the 5th day of April, 1994, by David F. Ranney, an individual, of 3539 Courtdale Drive, Dallas, Texas 75234, ("Ranney"), and ACCESS PHARMACEUTICALS, INC, a Texas corporation having its principal place of business at 2600 N. Stemmons Freeway, Suite 210, Dallas, Texas 75207 ("Access").

#### RECITALS

WHEREAS, Access desires to purchase from Ranney, and Ranney agrees to sell to Access, the Patents (as defined in Section 1.1 below), upon the term and conditions contained herein; and

WHEREAS, Access desires to terminate the Licenses (as defined in Section 1.2 below), and Ranney is willing to terminate the Licenses upon the consummation of the transactions contemplated by this Agreement;

NOW, THEREFORE, for and in consideration of the premises, mutual covenants and agreements contained herein, and intending to be legally bound hereby, the parties hereto hereby agree as follows:

# ARTICLE 1

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## PURCHASE AND SALE OF PATENTS

-----

- 1.1 Purchase and Sale. Subject to the terms and conditions of this Agreement, at the closing of the transactions contemplated hereby (the "Closing"), Ranney shall sell, transfer, convey, assign, deliver and set over (collectively, "Transfer") to Access in the form of an assignment as set forth on Exhibit AA hereto, and Access shall purchase, acquire and accept from Ranney, all of Ranney's right, title and interest in, to and under all of the patents and patent applications listed on Schedule A hereto and all divisions, continuations, continuations-in-part, re-issues and extensions thereof (collectively, the "Patents").
- 1.2 Termination of Licenses. Subject to the terms and conditions of this Agreement, at the Closing, the existing Exclusive Technology Licensing Agreements between Access and Ranney, dated December 15, 1988 and February 28, 1989, respectively, and including the Addenda thereto, dated February 13, 1990 (collectively, the "Licenses"), shall terminate and be of no further effect, except that the provisions of the Licenses regarding indemnification and confidential information shall continue in full force and effect.
- 1.3 License to Ranney. Ranney retains the non-exclusive right to use the inventions and technology covered by or relating to the Patents (i) for his own research, teaching and other

academic related purposes, and (ii) after Ranney is no longer a full-time employee of Access, for research and development of uses or implementations of the inventions and technology improvements related to or dependent on the Patents. Ranney shall offer Access the first right to negotiate the acquisition of any new inventions or technology improvements developed by Ranney relating to the Patents upon terms and conditions mutually satisfactory to both parties prior to assigning and granting any rights to such new inventions and technology to any other party. Ranney shall also have the right to publish articles and other materials regarding the inventions and technology covered by or relating to the Patents, provided, however, that such publications are submitted to Access prior to publication and provided further that Access consents to the publication of such publications, which consent shall not be unreasonably withheld.

1.4 Purchase Price. As full consideration of the assignment of the Patents, and termination of the Licenses, Access shall pay and hereby agrees to pay to Ranney, for his benefit and that of his personal representative and

heirs, the following amounts, in addition to all other salary, bonus, incentive or other compensation to which Ranney may be entitled as an employee, officer and/or director of Access:

(a) The following amounts to be paid as follows:

\$ 7,500	in cash on the date the Agreement is executed
\$ 15,000	in cash on 1-31-95 for calendar year 1994
\$ 25,000	in cash on 1-31-96 for calendar year 1995
\$ 50,000	in cash on 1-31-97 for calendar year 1996
\$ 75,000	in cash on 1-31-98 for calendar year 1997
\$150,000	in cash on 1-31-99 for calendar year 1998
\$150,000	in cash on 1-31-00 for calendar year 1999
\$200,000	in cash on 1-31-01 and on January 31 of each year
	thereafter for the preceding calendar year, as long
	as one or more of the Patents is still in force.

- (b) For calendar year 1998 and thereafter, Access will also pay Ranney not later than January 31 of the following year, a royalty of three quarters of one percent (0.75%) of gross revenues in excess of \$20 million (\$26.5 million for calendar year 2000 and thereafter) in any way derived from the Patents and any substitutions from the Patents, including, but not limited to gross revenues from product options, licenses and sales, but excluding proceeds from reimbursements of direct research costs and equity and debt financings. The royalty shall be based on revenues booked in accordance with generally accepted accounting principles for the calendar year then most recently ended, and paid not later than the following January 31 of each year throughout the life of the Patents.
- (c) The foregoing consideration shall not be abated or reduced in the event that any Patent is determined to be invalid or unenforceable and for purposes of determining the amounts to be

paid pursuant to this Section 1.3, the life of any such Patent shall be deemed to be the life of such Patent had it not been determined to be invalid or unenforceable.

All of the foregoing herein referred to as the "Purchase Price."

ARTICLE II

THE CLOSING

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- 2.1 Time and Place of Closing. The Closing shall take place at 10:00 a.m., Dallas time, on April 5, 1994 or such earlier or later date as may be mutually agreed upon by the parties hereto ("the Closing Date"), at Access' offices, or at such other time or place as may be mutually agreed upon by the parties.
- 2.2 Deliveries. At the Closing, (a) Ranney shall deliver to Access an assignment in the form set forth on Exhibit AA and other good and sufficient instruments of Transfer, in form and substance reasonably satisfactory to Access and its counsel and to Ranney and his counsel as shall be effective to vest in Access all of Ranney's right, title and interest in, to and under the Patents; and (b) each party shall deliver to the other party such other documents, instruments and certificates as may be reasonably requested by such other party or its counsel to effectuate and perfect the transactions contemplated by this Agreement.
- 2.3 Further Assurances. In addition to the actions, documents and instruments specifically required to be take or delivered by this Agreement, at the Closing or from time to time thereafter, and the parties hereto shall take such other actions, and execute and deliver such other documents and instruments, as the other party or its counsel may reasonably request in order to effectuate and perfect the transactions contemplated by this Agreement.

#### PRESENTATIONS/WARRANTIES AND COVENANTS OF ACCESS

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Access hereby represents and warrants to Ranney as follows:

- 3.1 Organization and Good Standing: Access is a corporation duly organized, validly existing and in good standing under the Laws of the State of Texas and has all requisite power and authority, corporate and otherwise, to own, operate and lease its properties and assets and to conduct its business as they are now being owned, operated, leased and conducted.
- 3.2 Power and Authority. Access has all requisite power and authority, corporate and otherwise, to enter into this Agreement and consummate the transactions contemplated hereby. The

execution and delivery of this Agreement by Access, the performance by Access of its obligations hereunder and the consummation of the transactions contemplated hereby have been duly and validly authorized by all corporate and other actions on the part of Access required by applicable law, its certificate or articles of incorporation or by-laws or otherwise. This Agreement constitutes the legal, valid and binding obligation of Access, enforceable against it in accordance with its terms, except as the same may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws now or hereafter in effect relating to creditors' rights generally.

3.3 No Violation. To the best knowledge of Access, neither the execution and delivery of the Agreement, the performance by Access of its obligations hereunder, nor the consummation of the transactions contemplated hereby, will (a) contravene any provision of its articles of incorporation or by-laws; or (b) violate, be in conflict with, constitute a default under, or accelerate the maturity of any debt or obligation of Access under, any note, bond, license, mortgage or indenture, or any material lease, contract, agreement, instrument or commitment, to which Access is a party or by which it or any of its assets or properties may be bound.

Access hereby covenants to Ranney as follows:

- 3.4 Patents. Access will exercise all appropriate diligence to maintain the Patents in force and to commercialize the Patents. Access will notify Ranney at least thirty (30) days in advance of all actions, agreements and filings with respect to the Patents. If access determines that maintenance of any Patent is not in the best interests of Access, it will notify Ranney at least thirty (30) days in advance of such determination and, if Ranney so elects, assign to Ranney all right, title and interest of Access in, to and under such Patent. Further, without Ranney's prior written consent, Access will not (i) grant any exclusive license for substantially all of the rights to make, use or sell inventions to any Patent or to sublicense substantially all of the rights to make, use or sell inventions under any Patent, or (ii) take or acquiesce to any action that would affect the validity, ownership, or scope of any Patent or amend the claims and specifications of any Patent.
- 3.5 Patents Assignments. Access will not assign, pledge or otherwise create any security interest in the Patents without Ranney's prior written consent, which shall not be unreasonably withheld.
- 3.6 Reports. Access shall within thirty (30) days after the last day of each calendar quarter render to Ranney a statement showing the details for such calendar quarter of all gross revenues derived from the Patents and any substitutions for the Patents, including without limitations a description of all transactions giving rise to any such gross revenues and copies of all reports

submitted by any sublicensees. Further, Access shall, on or before the date of payment of any amount payable pursuant to section 1.3 of this Agreement, render to Ranney a statement showing the details for the calendar year for which such payment is made of all gross revenues derived from the Patents and any substitutions for the Patents, all transactions giving rise to such gross revenues, copies of all reports submitted by any sublicensees which have not been other wise provided to Ranney, and a computation of the Purchase Price Amount payable with respect to such calendar year. Within ninety (90) days after

the end of each calendar year, Access shall also provide Ranney with an audited statement or report of the gross revenues derived from the Patents and any substitutions for the Patents during the preceding calendar year, which statement or report shall be prepared by a firm of independent certified public accountants reasonably acceptable to Ranney and shall contain a certificate of such accountants in form and substance reasonably satisfactory to Ranney.

3.7 Records and Audit Rights. Access shall keep proper books of accounts and accurate and complete records and the supporting invoices and documentation showing all matters connected with revenues derived from the Patents and any substitutions for the Patents, including without limitation licensing revenues. Access shall allow Ranney and his agents, attorneys, and accountants full access at all reasonable times to inspect and make copies of or extracts from such books, records, invoices and documents as may be reasonably necessary for the purpose of verifying the amount of the Purchase Price to be paid pursuant to this Agreement. All copies and extracts of confidential records of Access shall be retained by Ranney in a confidential manner, provided that such copies and extracts may be used by or disclosed to Ranney's advisors. accountants, and attorneys, or used or disclosed to enforce this Agreement, or disclosed in accordance with any subpoena or order of any court or governmental agency, or disclosed on a confidential basis to potential assignees of Ranney. All such audits and verifications shall be at Ranney's sole expense, provided, however, that if the results of any such audit or inspection indicate that the amount of gross revenues derived from the Patents and any substitutions for the Patents were understated by two percent (2%) or more, then Access shall promptly reimburse Ranney for such audit or inspection expenses, as well as the difference in the amount payable hereunder.

3.8 Indemnification. ACCESS AGREES TO FULLY INDEMNIFY AN D HOLD RANNEY AND HIS HEIRS, LEGAL REPRESENTATIVES, ADMINISTRATORS, ASSIGNS AND AGENTS ("THE INDEMNIFIED PARTIES") HARMLESS FROM AND AGAINST ANY AND ALL LIABILITIES, LOSSES, COSTS, FINES, PENALTIES, JUDGEMENTS, AND EXPENSES (INCLUDING WITHOUT LIMITATION ALL ATTORNEYS' FEES, EXPERTS' FEES AND COURT COSTS) WHICH MAY BE ASSERTED AGAINST ANY OF THE INDEMNIFIED PARTIES ARISING OUT OF, DIRECTLY OR INDIRECTLY, OR IN ANY WAY RELATING TO (i) ACTS OR OMISSIONS OF ACCESS OR ITS EMPLOYEES, AGENTS, OR ASSIGNEES, OR OF LICENSEES OF RIGHTS UNDER ANY PATENT OR SUBSTITUTION FOR ANY PATENT ("THE ACCESS PARTIES") IN CONNECTION

WITH THIS AGREEMENT OR ANY LICENSES OF RIGHTS UNDER ANY PATENT OR SUBSTITUTION FOR ANY PATENT (INCLUDING WITHOUT LIMITATION LICENSES GIVEN PURSUANT TO SECTION 6.02 OF THIS AGREEMENT), (ii) THE USE, MISUSE OR EXPLOITATION OF THE PATENTS BY ANY OF THE ACCESS PARTIES, AND (iii) THE SALE OR USE OF ANY PRODUCT OR MATERIAL COVERED BY ANY PATENT OR SUBSTITUTION FOR ANY PATENT OR A SUBSTITUTION FOR ANY PATENT OR INCORPORATING ANY INVENTION DISCLOSED UNDER ANY PATENT OR A SUBSTITUTION FOR ANY PATENT, REGARDLESS OF WHETHER SUCH ACTION IS BASED ON NEGLIGENCE, STRICT LIABILITY, PRODUCT LIABILITY, OR OTHERWISE. IT IS THE EXPRESS INTENTION OF ACCESS AND RANNEY THAT THE INDEMNIFICATION CONTAINED IN THIS SECTION 3.8 SHALL INDEMNIFY THE INDEMNIFIED PARTIES FOR ALL LIABILITIES, LOSSES, COSTS, FINES, PENALTIES, JUDGEMENTS AND EXPENSES (INCLUDING WITHOUT LIMITATION ALL ATTORNEYS' FEES, EXPERTS' FEES AND COURT COSTS) ARISING OUT OF OR RELATING TO THE NEGLIGENCE, STRICT LIABILITY, OR PRODUCT LIABILITY OR ANY OF THE INDEMNIFIED PARTIES. The indemnification contained in this Section 3.8 shall be in addition to any other indemnification to which Ranney or any of the other Indemnified Parties may be entitles as a director or officer of Access or otherwise.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES OF RANNEY

Ranney hereby represents and warrants to Access as follows:

4.1 Patents. THE ASSIGNMENT MADE PURSUANT TO THIS AGREEMENT IS MADE WITHOUT WARRANTY OF TITLE, VALIDITY, ENFORCEABILITY, NON-INFRINGEMENT, OR OTHERWISE. Ranney and Access represent and acknowledge that they have received

(i) a copy of the patent assignment dated April 30, 1987, from the University of Texas Southwestern Medical Center at Dallas ("UT") to Ranney, pursuant to which UT retained a non-exclusive license to use certain patent rights: (ii) a copy of

UT retained a non-exclusive license to use certain patent rights; (ii) a copy of the license of certain patent rights to Yamanouchi Pharmaceutical Company, Ltd.,

(iii) a copy of patent counsel's written report dated March 1, 1994, a copy os

which is attached hereto as Schedule B and incorporated herein and made a part hereof, and (iv) a copy of the opposition filed in Munich, Germany, a copy of which is attached hereto as Schedule C.

Ranney hereby covenants to Access as follows:

- 4.2 Delivery. At the closing Date Ranney shall deliver all Patents and related patent documents to Access, and will thereafter cooperate in the timely filing of all documents necessary to complete the assignment of Patents to Access.
- 4.2 Maintenance of Patents. Except as may be required by Ranney's duties as a full-time employee of Access, Ranney shall not be obligated to maintain the Patents or to assist Access in maintaining the Patents. Ranney may, however, at his sole option, assist Access in maintaining the Patents.
- 4.4 Obligations of Ranney; Expenses and Compensation. Ranney's obligations under this Agreement, including without limitation his obligations under Article II of this Agreement, shall be subject to Access' paying or reimbursing to Ranney the following: (a) all expenses, including without limitation all attorneys' fees and expenses, incurred by Ranney in connection with (i) the negotiation and performance of this Agreement, all assignments of the Patents, and all other documents and instruments to be delivered or executed in connection with this Agreement and the assignments of the Patents (including without limitation all attorneys' fees and expenses incurred in connection with any subpoena or discovery action trial or other proceeding), (ii) any license of rights under the Patents, and (iii) any loan to or investment in Access; (b) if Ranney is not a full-time employee of Access at the time of performance of such obligations; and (c) if Ranney is subpoenaed to testify at any trial or other proceeding or at any deposition regarding or relating to any of the Patents or the is Agreement or otherwise relating to the Patents or Access; business, and if Ranney is not a full-time employee of Access a thaT time of his receipt of any such subpoena and at all times thereafter through the completion of any time expended to fulfill the obligations of such subpoena, reasonable compensation for Ranney's time expended in the preparation for and attendance at such proceeding or depositions. Any compensation to be paid to Ranney under this Section 4.4 shall be reasonably satisfactory to Ranney. Access shall, at Access' expense, take such measures as may be reasonably requested by Ranney to reduce the time and effort to be expended by Ranney in the performance of his obligations under this Agreement or in testifying as a witness, including without limitation hiring assistants and professionals reasonably satisfactory to Ranney to assist Ranney and providing Ranney with such offices, facilities, and equipment as Ranney may reasonably request. Nothing in this Agreement shall impose any obligation on Ranney to defend or maintain any Patent or to defend any action or proceeding in which a claim or counterclaim is made for revocation of, or contesting the validity or scope of, any Patent or to prosecute any action for infringement or alleged infringement of any Patent, but if Ranney does assist Access in defending or maintaining any Patent or defending or prosecuting any actions with respect to any Patent, the provisions of this Section 4.4 shall apply.

ARTICLE V

# SURVIVAL OF REPRESENTATIONS AND WARRANTIES

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Not withstanding (a) the making of this Agreement, (b) any examination or investigation made by or on behalf of the parties hereto and (c) the Closing hereunder, (i) the representations and warranties of the parties hereto contained in this Agreement or in any of the agreements, instruments or documents relating hereto shall survive the execution an delivery of this Agreement and the closing for a period of one year from and after the Closing Date and (ii) the covenants and agreements of the

parties hereto contained in this Agreement or in any of the agreements, instruments or documents relating hereto, shall survive until fully performed or fulfilled (unless non-compliance with such covenants or agreements is waived in writing by the party hereto entitled to such performance).

# TERMINATION OF PATENTS ASSIGNMENT

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- 6.01 Termination. Ranney's assignment of the Patents to Access shall terminate and be of no further force and effect, and all right, title and interest in, to and under the Patents shall revert to and vest in Ranney, upon the occurrence of any of the following events:
- (a) If Access shall fail to proceed in good faith to commercially develop the Patents, after written notice to Access and Access fails to cure such deficiency within 90 days after such notice;
- (b) If Access shall file a petition in bankruptcy, become insolvent, or become the subject of any involuntary bankruptcy, receivership or similar proceeding and fail to have such involuntary action dismissed within 90 days after the date of the filing; or
- (c) If Access shall have made an assignment for the benefit of any creditors or if any governmental authority or any court at the instance thereof shall take possession of any substantial part of the property of, or assume control over, the affairs or operations of Access; or
- (d) If Access shall fail to pay the Purchase Price or any part thereof or any amounts due to Ranney pursuant to terms of this Agreement, and shall fail to cure such default within 10 days after receipt of written notice of nonpayment from Ranney.
- (e) If Access shall have assigned, pledged, or otherwise created any security interest in the Patents or entered into any agreement to do any of the foregoing without Ranney's prior written consent; or if Access shall have granted any exclusive license for substantially all of the right to make, use or sell inventions to any Patent or to sublicense substantially all of the rights to make, use or sell inventions under any Patent or shall have taken or acquiesced to any action that would affect the validity, ownership or scope of any Patent or shall have amended the claims and specifications or any Patent without the prior written consent of Ranney; or
- (3) If Access shall have committed a breach of any other covenant or agreement contained in this Agreement and shall not have remedied such breach within thirty (30) days after written notice thereof is given to Access by Ranney.
- 6.02 License. In the event this Agreement and the assignment of the Patents terminates pursuant to Section 6.01 above, Ranney or his assigns shall immediately offer to each of Access' licensees who have any rights under the Patents a direct license to make, use, or sell an invention covered by such Patents on terms and conditions generally as favorable as those contained in any such Access license to such licensee does not violate any of the terms of this Agreement, (ii) Ranney or his assigns shall not be obligated to perform any of the obligations of Access under the license by Access to such licensee other than to allow such licensee to make, use or sell products covered by such Patent, and (iii) any such license by Ranney or his assigns shall be without any warranties or representations on the part of Ranney or his assigns with respect to title or infringement. Ranney or his assigns shall promptly take such reasonable action as may be necessary and appropriate to negotiate and document the license arrangements contemplated by this Section 6.02, which license or licenses will be effective simultaneously with the termination and reversion pursuant to Section 6.01.

ARTICLE VII

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# MISCELLANEOUS

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7.01 Arbitration. The Parties will endeavor to settle amicably any dispute regarding any payments under this Agreement. Failing of such a settlement, any dispute regarding the amounts payable by Access to Ranney under

this Agreement shall be finally settled by arbitration, in accordance with the commercial rules of arbitration of the American Arbitration Association then in effect. The arbitration will be held in Dallas, Texas. The dispute or differences shall be referred to a single arbitrator, if the Parties agree upon one, or otherwise three (3) arbitrators, one to be appointed by written notice of each Party to the other and a third to be appointed by the first two (2) arbitrators selected by the Parties. If a Party shall refuse or neglect to appoint an arbitrator within thirty (30) days after the other Party shall have served a written notice of such other Party's choice and requesting that the first-mentioned Party make its choice, then the arbitrator first appointed shall, at the request of the Party appointing him, proceed to hear and determine the matters in difference as if he were a single arbitrator appointed by both Parties. The arbitrators shall base their decision in accordance with an based upon all the provisions of this Agreement and any other Agreements referenced herein, to the extent such other agreements are not superseded by this Agreement or subsequent agreements between the Parties. In making their decision, the arbitrators shall apply the substantive law of the State of Texas. The decision of a majority of the arbitrators shall be final and binding upon each Party, and judgement upon the award may be entered in any court of competent jurisdiction. Before rendering their final decision, the arbitrators will first act as friendly, disinterested parties for the purpose of helping the Parties attempt to reach a compromise settlement on the points in dispute. The cost of arbitration will

be in the discretion of the arbitrators. Access shall pay all costs associated with the arbitration, including without limitation costs of the arbitration itself (including but not limited to arbitrator fees and the attorneys' fees and experts' fees of Ranney).

- 7.2 Amendment; Waiver. Neither this Agreement, nor any of the terms or provisions hereof, may be amended, modified, supplemented or waived, except by a written instrument signed by all of the parties hereto (or, in the case of a waiver, by the party granting such waiver). No waiver of any of the provisions of this Agreement shall be deemed to be or shall constitute a waiver of any other provision of this Agreement, nor shall such waiver constitute a continuing waiver. No failure of a party hereto to insist upon strict compliance by another party hereto with any obligation, covenant, or agreement shall be deemed to be or shall constitute a waiver of, or estoppel with respect to, any subsequent or failure.
- 7.3 Assignment. This Agreement and all of the terms and provisions hereof shall be binding upon and inure to the benefit of the parties hereto and their respective personal representatives, successors and assigns.
- 7.4 Governing Law. THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF TEXAS, WITHOUT GIVING EFFECT TO THE CONFLICT OF LAWS PRINCIPLES THEREOF. THIS AGREEMENT SHALL BE PERFORMABLE IN DALLAS, DALLAS COUNTY, TEXAS, AND ANY AND ALL ACTIONS AND PROCEEDINGS RELATING TO OR ARISING OUT OF THIS AGREEMENT OR THE ASSIGNMENTS OF THE PATENTS SHALL BE BROUGHT AND MAINTAINED IN A COURT OF COMPETENT JURISDICTION SITTING IN DALLAS COUNTY, TEXAS.
- 7.5 Entire Agreement. This Agreement embodies the entire agreement and understanding between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements, commitments, arrangements, negotiations or understandings whether oral or written, between the parties with respect to the subject matter hereof other than those expressly set forth or referred to herein.
- 7.6 Severability. Each term and provision of this Agreement constitutes a separate and distinct undertaking, covenant, term and/or provision hereof. In the event that any term or provision hereof shall be determined to be unenforceable, invalid or illegal in any respect, such unenforceability, invalidity or illegality shall not affect any other term or provision hereof, but this Agreement shall be construed as if such unenforceable, invalid or illegal term or provision had never been contained herein.
- 7.7 counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which, when taken together, shall constitute one and the

same instrument.

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

#### ACCESS PHARMACEUTICALS, INC.

By: /s/Kerry P. Gray
Kerry Gray, President

/s/David F. Ranney
----David F. Ranney, an individual

EXHIBIT AA Page 1 of 4

# PATENT ASSIGNMENT

THIS ASSIGNMENT (the "Patent Assignment") is made as of the 5th day of April, 1994, by David F. Ranney, an individual, of 3539 Courtdale Drive, Dallas, Texas 75234 (the "Assignor"), and ACCESS PHARMACEUTICALS, INC., a Texas corporation having its principal place of business at 2600 N. Stemmons Freeway, Suite 210, Dallas, Texas 75207 (the "Assignee").

## WITNESSETH

WHEREAS, Assignor and Assignee have entered into that certain Patent Purchase Agreement (the "Purchase Agreement") dated as of the date hereof pursuant to which Assignor has agreed to sell, transfer, convey, assign, deliver and set over unto Assignee, and Assignee has agreed to purchase, acquire and accept from Assignor, all of Assignor's right, title and interest in, to and under the patents and patent applications listed of Schedule A hereto (collectively, the "Patents"), subject to the terms and conditions of the Purchase Agreement;

NOW, THEREFORE, for and in consideration of the Purchase Price, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Assignor hereby agrees as follows:

- 1. The capitalized terms used in this Patent Assignment that are not otherwise defined herein shall have the respective meanings ascribed to such terms in the Purchase Agreement unless the context hereof otherwise requires.
- 2. Subject to the terms and conditions of the Purchase Agreement and this Patent Assignment, the Assignor hereby sells, transfers, conveys, assigns and sets over unto the Assignee the Assignor's entire right, title and interest in, to and under each of the Patents set forth on Schedule A, including, without limitation, all divisions, continuations, continuations-in-part, reissues, renewals and extensions thereof, all rights to priority, and all claims for profits or damages by reason of past infringement of any of the Patents, together with the right to sue for and collect such profits and damages for its own use and enjoyment and for the use and enjoyment of its successors and assigns.
- 3. The Assignor hereby authorizes the Commissioner of Patents and Trademarks of the United States and the empowered officials of all other governmental authorities or agencies to issue or transfer all of the Patents to

the Assignee as assignee of the entire right, title and interest therein or otherwise as the Assignee may direct, in accordance with this Patent Assignment.

## EXHIBIT AA Page 2 of 4

- 4. Subject to the terms of the Purchase Agreement, the Assignor shall at any time and from time to time upon request, at the expense of the Assignee, promptly execute and deliver any and all papers and documents and do all other lawful acts as the Assignee, in its reasonable judgement, shall deem to be necessary or desirable in order to perfect the title to the Patents in the Assignee and its successors and assigns.
- 5. Each copy of this Patent Assignment which is signed by the Assignor in order to facilitate the recording of the Assignee's interest in the Patents shall be deemed an original.
- 6. The agreements, obligations, covenants, representations and warranties of the Assignor and the Assignee contained in the Purchase Agreement are not merged into this Patent Assignment and shall, to the extent provided in the Purchase Agreement, survive the execution and delivery of this Patent Assignment and the consummation of the transactions contemplated by the Purchase Agreement.
- 7. The Assignor's assignment of the Patents to the Assignee shall terminate and be of no further force and effect, and all right, title and interest in, to and under the Patents, including without limitation all divisions, continuations, continuations-inpart, reissues, renewals and extensions thereof, all rights to priority, and all claims for profits or damages by reason of past infringement of any of the Patents, together with the right to sue for and collect such profits and damages for its own use and enjoyment and for the use and enjoyment of its successors and assigns, shall revert to and vest in the Assignor upon the occurrence of certain events and under the terms and conditions specified in the Purchase Agreement.
- 8. This Patent Assignment and all of the terms and provisions hereof shall inure to the benefit of the Assignee and its successors and assigns and shall be binding upon the Assignor and his personal representative and heirs.
- 9. THIS PATENT ASSIGNMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF TEXAS, WITHOUT GIVING EFFECT TO THE CONFLICT OF LAWS PRINCIPALS THEREOF. This Agreement shall be performable in Dallas, Dallas County, Texas, and any and all actions and proceedings relating to or arising out of this Assignment shall be brought and maintained in a court of competent jurisdiction sitting in Dallas County, Texas.

EXHIBIT AA Page 3 of 4

IN WITNESS WHEREOF, the Assignor and Assignee have caused this Patent Assignment to be duly executed and delivered as of the day and year first above written.

ASSIGNOR:

/s/ David F. Ranney
----David F. Ranney, an individual

ASSIGNEE:

ACCESS PHARMACEUTICALS, INC.

By:/s/ Kerry P. Gray

Name:Kerry P. Gray Title: President

STATE OF TEXAS

[Section Mark]

[Section Mark]

COUNTY OF DALLAS [Section

[Section Mark]

This instrument was acknowledged before me, the undersigned authority, on this 5th day of April, 1994, by David F. Ranney.

/s/ Yvonne L. Clark
----Notary Public, State of Texas

STATE OF TEXAS

[Section Mark]

[Section Mark]

Notary Seal

COUNTY OF DALLAS [Section Mark]

This instrument was acknowledged before me, the undersigned authority, on this 5th day of April, 1994, by Kerry P. Gray, President of ACCESS Pharmaceuticals, Inc., a Texas corporation, on behalf of said corporation.

/s/ Yvonne L. Clark
----Notary Public, State of Texas

EXHIBIT AA Page 4 of 4

#### SCHEDULE A

RANN:001, US Patent 4,925,678
RANN:002AU, Australian Patent 607494
RANN:002CA, Canadian Application 565,119-1
RANN:002EP, European Patent 0352295
RANN:002JP, Japanese Application 503579
RANN:003, US Patent 5,108,759
RANN:005-2, US Patent 5,260,050
RANN:005AU, Australian Patent 628403
RANN:005CA, Canadian Application 614,494
RANN:005EP, European Application 89309983.8
RANN:005TW, Taiwanese Patent N162306
RANN:007, US Patent 5,213,788
RANN:013, US Application 08/160,085
RANN:016, US Application 08/194,791.

# FIRST AMENDMENT to PATENT PURCHASE AGREEMENT

This First Amendment to the Patent Purchase Agreement by and between Access Pharmaceuticals, Inc. ("ACCESS"), formerly Chemex Pharmaceuticals, Inc. ("Chemex"), successor to ACCESS pursuant to a merger upon the terms and conditions contained in the Merger Agreement (defined herein) and David F. Ranney ("Ranney") is dated this 23rd day of January, 1996, and is to be effective from and after the Effective Time as set forth in Section 1.3 of the Merger Agreement (defined herein).

#### RECITALS

- A. On April 5, 1994, ACCESS Pharmaceuticals, Inc. and Ranney entered into a Patent Purchase Agreement ("Agreement") and a Patent Assignment Agreement ("Assignment") which have been continuously in effect since such date.
- B. The parties now desire: (1) to amend the Agreement, as provided herein, to comply with the requirements of Paragraph 4 of that certain Stockholder's Agreement by and between Ranney and Chemex dated as of October 3, 1995; and (2) to assure that the patent assignments are filed with and under the "Assignment" and the "Agreement" as further amended herein. The Stockholder's Agreement is an integral part of the terms and conditions of that certain Agreement of Merger and Plan of Reorganization dated October 3, 1995, as amended and restated as of October 31, 1995, by and between ACCESS and Chemex ("Merger Agreement"). Modification of the Agreement according to Article "4." of the Stockholder's Agreement is a condition precedent to the performance by Chemex of its obligations under the Merger Agreement.

## **AGREEMENT**

NOW, THEREFORE, in consideration of the mutual agreements contained herein and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, ACCESS and Ranney hereby agree as follows:

- 1. Under Section 1.4, Subsection "(a)" is hereby deleted in its entirety and the following is substituted therefor:
  - "(a) The following amount to be paid as follows:

\$ 7,500	in cash on the date the Agreement is executed
\$15,000	in cash on 1-31-95 for calendar year 1994
\$25,000	in cash on 1-31-96 for calendar year 1995
\$50,000	in cash on 1-31-97 for calendar year 1996

1

additionally, so long as one or more of the Patents remains in effect and ACCESS or its successors or assigns is developing technology under such Patents, an amount in cash on 1-31-98 and on the January 31 each year thereafter, equal to 105% of the payment made pursuant to this subsection 1.4(a) in the immediately preceding calendar year (e.g., the Section 1.4(a) payment for 1-31-98 would be \$52,500 (1-31-97 payment x 105%, etc.))."

2. Section 1.4(c) is hereby amended by changing the reference to "1.3" which immediately follows the word "Section" to read "1.4".

conditions and provisions of the Agreement shall remain in full force and effect

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

ACCESS PHARMACEUTICALS, INC., a Texas corporation

By: /s/ Kerry P. Gray
----Kerry P. Gray, President

/s/ David F. Ranney

David F. Ranney, an individual

# Consent of Independent Auditors'

The Board of Directors and Stockholders ACCESS Pharmaceuticals, Inc.:

We consent to the incorporation by reference in Registration Statement Nos. 33-42052, 33-32137 and 33-22750 on Form S-3 and 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 29, 1996, relating to the balance sheets of ACCESS Pharmaceuticals, Inc. as of December 31, 1995 and 1994, and the related statements of operations, stockholders' equity, and cash flows for each of the years in the three year period ended December 31, 1995, which report appears in the December 31, 1995 annual report on Form 10-K of ACCESS Pharmaceuticals, Inc.

KPMG Peat Marwick LLP

Dallas, Texas March 29, 1996

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THIS SCHEDULE CONTAINS SUMMARY FINANCIAL INFORMATION FROM THE CONSOLIDATED BALANCE SHEET AND THE CONSOLIDATED STATEMENT OF INCOME FILED AS PART OF THE ANNUAL REPORT ON FORM 10-K AND IS QUALIFIED IN ITS ENTIRETY BY REFERENCE TO SUCH ANNUAL REPORT ON FORM 10-K.

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