

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

PRE-EFFECTIVE AMENDMENT NO.1 TO  
FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

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

Delaware	3841
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(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)

83-0221517

-----  
(I.R.S. Employer  
Identification No.)

2600 Stemmons Freeway, Suite 176  
Dallas, Texas 75207 (214) 905-5100  
(Address, including zip code, and telephone number,  
including area code, of registrant's principal executive offices)

Kerry P. Gray  
President and Chief Executive Officer  
Access Pharmaceuticals, Inc.  
2600 Stemmons Freeway, Suite 176  
Dallas, Texas 75207  
(214) 905-5100  
(Name, address, including zip code, and  
telephone number, including area code, of agent for service)

with copies to:

John J. Concannon III  
Bingham Dana LLP  
150 Federal Street  
Boston, MA 02110  
(617) 951-8000

Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement is declared effective.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. //

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. /x/

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. //

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. //

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. //

## CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	Proposed Maximum Amount to be Registered	Offering Price Per Share(1)
Common Stock \$.01 par value per share	934,605 shares (2)	\$5.875

Proposed Maximum Aggregate Offering Price (1)	Amount of Registration Fee
\$ 5,490,804	\$ 1,449.57 (3)

(1) Estimated solely for the purpose of determining the registration fee. Calculated in accordance with Rule 457(c) under the Securities Act of 1933 based on the average of the high and low prices as reported by the American Stock Exchange on December 12, 2000.

(2) Includes 31,904 shares issuable to certain selling stockholders upon exercise of warrants for the purchase of shares of the Registrant's Common Stock (see "Selling Stockholders").

(3) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective, on such date as the Commission, acting pursuant to Section 8(a), may determine.

## PROSPECTUS

Access Pharmaceuticals, Inc.

Information contained in this prospectus is subject to completion or amendment. A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold until the registration statement becomes effective. This prospectus is not an offer to sell and is not a solicitation of an offer to buy these securities in any state in which an offer, solicitation or sale is not permitted.

Subject to completion, January 16, 2001.

934,605 Shares of  
Common Stock, \$.01 par value

This prospectus relates to the sale of up to 934,605 shares of our common stock, or the Shares, \$.01 par value per share, by certain stockholders of ours, the Selling Stockholders, for their respective accounts.

We will not receive any proceeds from the sale of the Shares by the Selling Stockholders. None of the Shares have been registered prior to the filing of the Registration Statement of which this Prospectus is a part.

On January 12, 2001, the last sale price of our Common Stock was \$5.125 per share, as reported by the American Stock Exchange, or AMEX, under the symbol AKC.

Investing in the common stock involves risks. For a discussion of certain factors you should consider, see "Risk Factors" beginning on Page 2.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus is \_\_\_\_\_, 2001

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### RISK FACTORS

This offering involves a high degree of risk. You should carefully consider the risks described below and the other information in this prospectus before purchasing our common stock.

We have experienced a history of losses and we expect to incur future losses.

We have recorded minimal revenue to date and we have incurred a cumulative operating loss of approximately \$30.3 million through September 30, 2000. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop target candidates and from the associated administrative costs. We expect to incur significant additional operating losses over the next several years. We also expect cumulative losses to increase substantially due to expanded research and development efforts and preclinical and clinical trials.

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

Our ability to achieve significant revenue or profitability depends upon our ability to successfully complete the development of drug candidates, to develop and obtain patent protection and regulatory approvals for our drug candidates and to manufacture and commercialize the resulting drugs. We have not received significant royalties for sales of our amlexanox products to date and we may not receive significant revenues or profits from the sale of these products in the future. Furthermore, we may not be able to ever successfully identify, develop, commercialize,

patent, manufacture, market and obtain required regulatory approvals for any additional products. Moreover, even if we do identify, develop, commercialize, patent, manufacture, market and obtain required regulatory approvals for additional products, we may not receive revenues or royalties from commercial sales of these products for a significant number of years, if at all. Therefore, our proposed operations are subject to all the risks inherent in the establishment of a new business enterprise. In the next few years, our revenues may be limited to any amounts that we receive under strategic partnerships and research or drug development collaborations that we may establish and we cannot assure you that we will be able to establish any such relationships on terms acceptable to us. We cannot assure you that we will achieve or maintain profitability in the future and our failure to receive significant revenues or to achieve profitable operations would impair our ability to sustain operations.

We may not successfully commercialize our drug candidates.

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

The success of our research and development activities, upon which we primarily focus, is uncertain.

Our primary focus is on our research and development activities and the commercialization of compounds covered by proprietary biopharmaceutical patents. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual research and development costs, therefore, could exceed budgeted amounts and estimated time frames may require extension. Cost overruns, unanticipated regulatory delays or demands, unexpected adverse side effects or insufficient therapeutic efficacy will prevent or substantially slow our research and development effort and our business could ultimately suffer. We anticipate that we will remain principally engaged in research and development activities for an indeterminate, but substantial, period of time.

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We may be unable to obtain necessary additional capital to fund operations in the future.

We require substantial capital for our development programs and operating expenses, to pursue regulatory clearances and to prosecute and defend our intellectual property rights. Although we

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

- \* the results of our research and development and collaboration programs,
- \* the timing and results of preclinical trials,
- \* our ability to maintain existing and establish new collaborative agreements with other companies to provide funding to us,
- \* the technological advances and activities of competitors and other factors.

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

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

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

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

We have no experience in the manufacture of pharmaceutical products in clinical quantities or for commercial purposes and we may not be able to manufacture any new pharmaceutical products that we may develop, so we intend to establish arrangements with contract manufacturers to supply sufficient

quantities of products to conduct clinical trials and for the manufacture, packaging, labeling and distribution of finished pharmaceutical products if any of our potential products are approved for commercialization. If we are unable to contract for a sufficient supply of our potential pharmaceutical products on acceptable terms, our preclinical and human clinical testing schedule may be delayed, resulting in the delay of our submission of products for regulatory approval and initiation of new development programs, which could cause our business to suffer. Delays or difficulties in establishing relationships with manufacturers to produce, package, label and distribute our finished pharmaceutical or other medical products, if any, market introduction and subsequent sales of such products could cause our business to suffer. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by the U.S. Food and Drug Administration, or FDA. In this regard, the FDA will not issue a pre-market approval or product and establishment licenses, where applicable, to a manufacturing

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

We are subject to extensive governmental regulation which increases our cost of doing business and may affect our ability to commercialize any new products that we may develop.

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish their safety and efficacy. All of our drug candidates will require governmental approvals for commercialization, none of which have been obtained. Preclinical and clinical trials and manufacturing of our drug candidates will be subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product. We cannot assure you when we, independently or with our collaborative partners, might submit a New Drug Application, or NDA, for FDA or other regulatory review. Government regulation also affects the manufacturing and marketing of pharmaceutical products.

Government regulations may delay marketing of our potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval

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

The uncertainty associated with preclinical and clinical testing may affect our ability to successfully commercialize new products.

Before we can obtain regulatory approvals for the commercial sale of any of our potential drugs, the drug candidates will be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. We cannot assure you that preclinical or clinical trials of any future drug candidates will demonstrate the safety and efficacy of such drug candidates at all or to the extent necessary to obtain regulatory approvals. In this regard, for example, adverse side effects can occur during the clinical testing of a new drug on humans or animals which may delay ultimate FDA approval or even lead us to terminate our efforts to develop the drug for commercial use. Companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate and could cause our business, operating results and financial condition to suffer.

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

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. These risks will expand with respect to our drug candidates, if any, that receive regulatory approval for commercial sale and we may face substantial liability for damages in the event of adverse side effects or product defects identified with any of our products that are used in clinical tests or marketed to the public. We have product liability insurance for drug candidates that are undergoing human clinical trials. Product liability insurance for the biotechnology industry is generally expensive, however, if available at all, and we cannot assure you that in the future we will be able to obtain insurance coverage at acceptable costs or in a sufficient amount, if at all. We may be unable to

satisfy any claims for which we may be held liable as a result of the use or misuse of products which we have developed, manufactured or sold and any such product liability claim could adversely affect our business, operating results or financial condition.

We may incur significant liabilities if we fail to comply with stringent environmental regulations or if we did not comply with these regulations in the past.

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

Intense competition may limit our ability to successfully develop and market commercial products.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of these competitors have and employ greater financial and other resources, including larger research and development staffs and more effective marketing and manufacturing organizations, than us or our collaborative partners. We cannot assure you that our competitors will not succeed in developing technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

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

Our ability to successfully develop and commercialize our drug candidates will substantially depend upon the availability of reimbursement funds for the costs of the resulting drugs and related treatments.

The successful commercialization of, and the interest



of potential collaborative partners to invest in, the development of our drug candidates will depend substantially upon reimbursement of the costs of the resulting drugs and related treatments at acceptable levels from government authorities, private health

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insurers and other organizations, including health maintenance organizations, or HMOs. We cannot assure you that reimbursement in the United States or elsewhere will be available for any drugs that we may develop or, if available, will not be decreased in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our drugs, thereby adversely affecting our business. If reimbursement is not available or is available only to limited levels, we cannot assure you that we will be able to obtain collaborative partners to commercialize our drugs, or be able to obtain a sufficient financial return on our own manufacture and commercialization of any future drugs.

The market may not accept any pharmaceutical products that we successfully develop.

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

Trends toward managed health care and downward price pressures on medical products and services may limit our ability to profitably sell any drugs that we may develop.

Lower prices for pharmaceutical products may result from:

- \* third-party payers' increasing challenges to the prices charged for medical products and services;
- \* the trend toward managed health care in the United States and the concurrent growth of HMOs and similar organizations that can control or significantly influence the purchase of healthcare services and products; and
- \* legislative proposals to reform healthcare or reduce government insurance programs.

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

We may not be successful in protecting our intellectual property and proprietary rights.

Our success depends, in part, on our ability to obtain U.S. and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate our business without infringing the proprietary rights of third parties. Although Access is either the owner or licensee of technology to 13 U.S. patents and to 7 U.S. patent applications now pending, we cannot assure you that any additional patents will issue from any of the patent applications owned by, or licensed to, us. Furthermore, we cannot assure you that any rights we may have under issued patents will provide us with significant protection against competitive products or otherwise be commercially viable. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under such patents are still developing and there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. The patent position of a biotechnology firm is highly uncertain and involves complex legal and factual questions. We cannot assure you that any existing or future patents issued to, or licensed by, us will not subsequently be challenged, infringed upon, invalidated or circumvented by others. In addition, patents may have been granted to third parties or may be granted covering products or processes that are necessary or useful to the development of our drug candidates. If our drug candidates or processes are found to infringe upon the patents or otherwise impermissibly utilize the intellectual property of others, our development, manufacture and sale of such drug candidates could be severely restricted or

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prohibited. In such event, we may be required to obtain licenses from third parties to utilize the patents or proprietary rights of others. We cannot assure you that we will be able to obtain such licenses on acceptable terms, if at all. If we become involved in litigation regarding our intellectual property rights or the intellectual property rights of others, the potential cost of such litigation, regardless of the strength of our legal position, and the potential damages that we could be required to pay could be substantial.

Our business could suffer if we lose the services of, or fail to attract, key personnel.

We are highly dependent upon the efforts of our senior management and scientific team, including our President and Chief Executive Officer. The loss of the services of one or more of these individuals could seriously impede our success. We do not maintain any "key-man" insurance policies on any of our key employees and we do not intend to obtain such insurance. In addition, due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific and technical personnel. In view of the stage of our development and our research and development programs, we have restricted our hiring to research scientists and a small administrative staff and we have made no investment in manufacturing, production, marketing, product sales or regulatory compliance resources. If we develop pharmaceutical products that we will commercialize ourselves, however, we will need to hire additional personnel skilled in the clinical

testing and regulatory compliance process and in marketing and product sales. There is intense competition among major pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions for qualified personnel in the areas of our activities, however, and we may be unsuccessful in attracting and retaining these personnel.

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

Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.), Richard Stone and Howard P. Milstein currently beneficially own approximately 7.8%, 6.2% and 5.8% respectively, of our issued and outstanding common stock.

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

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

Substantial sales of our common stock could lower our stock price.

The market price for our common stock could drop as a result of sales of a large number of our presently outstanding shares. Currently, a significant percentage of the outstanding shares of our common stock are unrestricted and freely tradable or tradable under Rule 144. Shareholders holding approximately 560,000 shares of our common stock became eligible to sell such shares on January 11, 2001. Upon the effectiveness of this registration statement an additional 324,761 shares of our common stock will be eligible to be sold.

This prospectus contains forward-looking statements that involve risks and uncertainties. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" or the negative of such terms or other compatible terminology. These statements are only predictions

and involve known and unknown risks, uncertainties and other factors, including risks outlined under "Risk Factors", that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements.

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

#### ACCESS PHARMACEUTICALS, INC.

Access Pharmaceuticals is a Delaware corporation in the development stage. We are an emerging pharmaceutical company focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities. We have proprietary patents or rights to five technology platforms: synthetic polymers, bioerodible hydrogels, Residerm<sup>TM</sup>, carbohydrate targeting technology, and agents for the prevention and treatment of viral disease, including HIV. In addition, our partner Block Drug Company, or Block, is marketing in the United States Aphthasol<sup>TM</sup>, the first FDA-approved product for the treatment of canker sores. We are developing new formulations and delivery forms to evaluate this product in additional clinical indications. We have licensed the rights to amlexanox for the treatment of canker sores from Block for certain countries excluding the U.S. and the worldwide rights for certain additional indications including mucositis and oral diseases.

Access was founded in 1974 as Chemex Corporation, a Wyoming corporation, and in 1983 changed its name to Chemex Pharmaceuticals, Inc. Chemex changed its state of incorporation from Wyoming to Delaware on June 30, 1989. In connection with the merger of Access Pharmaceuticals, Inc., a Texas corporation, with and into Chemex on January 25, 1996, we changed our name to Access Pharmaceuticals, Inc. Our principal executive office is at 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207; our telephone number is (214) 905-5100.

#### RECENT DEVELOPMENTS

On November 30, 2000, we announced the results of a Phase IV European clinical study evaluating amlexanox 5% paste for the prevention of aphthous ulcers (canker sores). Amlexanox 5% paste was effective in preventing the formation of an ulcer when used at the first sign or symptom of the disease.

#### USE OF PROCEEDS

We will not receive any proceeds from the sale of shares by the Selling Stockholders.

#### 8 SELLING STOCKHOLDERS

The following table sets forth certain information

regarding the beneficial ownership of our common stock as of January 16, 2001 and as adjusted to reflect the sale of our common stock offered hereby, by each of the Selling Stockholders.

Except as indicated below, none of the Selling Stockholders has had any position, office or other material relationship within the past three years with us or our affiliates. In addition, except as provided herein, we believe, based on information provided to us by the Selling Stockholders, that each Selling Stockholder has sole voting and investment power with respect to the shares beneficially owned. For more information regarding the shares offered, see "Plan of Distribution" below.

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Name of Selling Stockholder	Shares Beneficially Owned Prior to Offering	Shares to be Beneficially Offered	Shares to be Beneficially Owned After Offering
Christine Ferer (3)	750,140 (1)	83,333	666,807 (1)
Lloyd Constantine (3)	750,140 (1)	25,000	725,140 (1)
F. Joseph Daugherty	12,426	5,250	7,176
GHK Associates	250,000	21,000	229,000
Joseph M. Hiffa (4)	800	800	-
Philip D. Kaltenbacher	250,000	208,000	42,000
LDR Associates	250,000	21,000	229,000
David A. Loewenstein	20,000	20,000	-
Medical Innovation Fund II	37,607	37,607	-
Edward L. Milstein (3)	750,140 (1)	185,544	564,593 (1)
Daniel Myers	2,224 (2)	2,224 (2)	-(2)
Panetta Partners, Ltd.	36,000	36,000	-
Marcia Riklis (3)	750,140 (1)	125,000	625,140 (1)
Linda Sincavage (3)	750,140 (1)	5,000	745,140 (1)
Eleanore Sniderman (3)	750,140 (1)	62,500	687,640 (1)
Marvin Sniderman (3)	750,140 (1)	66,667	683,473 (1)
Preston Tsao	93,552 (1)	29,680 (2)	63,872 (1)

</TABLE>

- (1) These share amounts include shares issuable upon exercise of warrants.
- (2) These share amounts represent shares issuable upon exercise of warrants.
- (3) These stockholders have entered into an agreement with Howard P. Milstein and among themselves that provides Mr. Milstein with sole voting power and dispositive power with regard to all of the shares of Common Stock.
- (4) Mr. Hiffa is an attorney at Bingham Dana LLP. The validity of our common stock to be sold in this offering is being passed on for us by Bingham Dana LLP.

#### PLAN OF DISTRIBUTION

The Selling Stockholders may sell or distribute the Shares directly to purchasers as principles or through one or more underwriters, brokers, dealers or agents as follows:

- \* from time to time in one or more transactions, which may involve block transactions;
- \* on any exchange or in the over-the-counter

market;

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- \* in transactions otherwise than in the over-the-counter market; or
- \* through the writing of options, whether such options are listed on an options exchange otherwise, on or settlement of short sales of, the Shares.

Any of these transactions may be effected at market prices at the time of sale, at prices related to such prevailing market prices, at varying prices determined at the time of sale or at negotiated or fixed price in each case as determined by the Selling Stockholder or by agreement between the Selling Stockholder and underwriters, brokers, dealers or agents, or purchasers. If the Selling Stockholder effect such transactions by selling Shares to or through underwriters, brokers, dealers or agents, the Selling Stockholders may compensate these underwriters, brokers, dealers or agents in the form of discounts, concessions or commissions from the Selling Stockholders or commissions from purchasers of securities for whom they may act as agent. These compensatory discounts, concessions or commissions may be in excess of those customary in the types of transactions involved as to particular underwriters, brokers, dealers or agents. The Selling Stockholders and any brokers, dealers or agents that participate in the distribution of the Shares may be deemed to be underwriters, and any profit on the sale of Shares by them and any discounts, concessions or commissions received by any of these underwriters, brokers, dealers or agents may constitute underwriting discounts and commissions under the Securities Act of 1933.

Under the securities laws of certain states, the Shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in certain states the Shares may not be sold unless the Shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

We will pay all of the expenses incident to the registration, offering and sale of the Shares to the public hereunder, estimated at \$18,000, other than commissions, fees and discounts of underwriters, brokers, dealers and agents. Those commissions, fees and discounts, if any, will be borne by the Selling Stockholder. We have agreed to indemnify the Selling Stockholders and any underwriters against certain liabilities under the Securities Act. We will not receive any of the proceeds from the sale of any of the Shares by the Selling Stockholders.

Certain of the underwriters, dealers, brokers or agents may have other business relationships with us and our affiliates in the ordinary course.

#### LEGAL MATTERS

The validity of our common stock to be sold in this offering is being passed upon for us by Bingham Dana LLP 150 Federal Street, Boston, Massachusetts 02110. Justin P. Morreale, David L. Engel and John J. Concannon III, partners of Bingham Dana LLP, and Joseph M. Hiffa, an attorney at Bingham Dana, LLP, beneficially own an aggregate of

182,299 shares of our common stock and warrants to purchase 834 shares of our common stock. Mr. Concannon is the corporate Secretary.

## EXPERTS

Our consolidated financial statements incorporated in this Prospectus by reference to our Annual Report on Form 10-K for the two year period ended December 31, 1999 have been so incorporated in reliance on the report of Grant Thornton LLP, independent certified public accountants, given on the authority of said firm as experts in accounting and auditing.

The consolidated statements of operations, stockholders' equity (deficit) and cash flows of Access Pharmaceuticals, Inc. and subsidiary for the year ended December 31, 1997, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent certified public accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

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

The cumulative statements of operations, stockholders' equity (deficit) and cash flows for the period February 24, 1988 (inception) to December 31, 1994 incorporated in this prospectus by reference to our Annual Report on Form 10-K have been so incorporated in reliance on the report of Smith, Anglin & Co., independent certified public accountants, given on the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN GET MORE INFORMATION

This prospectus constitutes a part of a registration statement on Form S-3 filed by us with the Securities and Exchange Commission, or SEC, under the Securities Act of 1933. This prospectus does not contain all of the information set forth in the Registration Statement, since we have omitted some parts in accordance with the SEC's rules and regulations. The SEC permits us to "incorporate by reference" the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file with the SEC will automatically update and supercede this information. Access has filed a Registration Statement on Form S-3 under the Securities Act of 1933 with the SEC with respect to common stock being offered pursuant to this prospectus. This prospectus omits certain information contained in the Registration Statement on

Form S-3, as permitted by the SEC. Refer to the Registration Statement on Form S-3, including exhibits, for further information about Access and the common stock being offered pursuant to this prospectus. Statements in this prospectus regarding provisions of certain documents filed with, or incorporated by reference in, the Registration Statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the Registration Statement, including the documents incorporated by reference or the exhibits, may be obtained without charge at the offices of the SEC listed below.

We are subject to the reporting requirements of the Securities Exchange Act of 1934 and therefore file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document we file at the public reference facilities of the SEC located at 450 Fifth Street N.W., Washington D.C. 20549. You may obtain information on the operation of the SEC's public reference facilities by calling the SEC at 1-800-SEC-0330. You can also access copies of such material electronically on the SEC's home page on the World Wide Web at <http://www.sec.gov>.

If you request a copy of any or all of the documents incorporated by reference, then we will send to you the copies you requested at no charge. However, we will not send exhibits to such documents, unless such exhibits are specifically incorporated by reference in such documents. We will also provide to each person to whom a copy of this prospectus has been delivered, upon special request and without charge, a copy of all documents filed from time to time by us with the SEC pursuant to the Securities Exchange Act of 1934. You should direct a request for such copies to Access Pharmaceuticals, Inc., 2600 Stemmons Frwy, Suite 176, Dallas, Texas 75207, attention Chief Financial Officer. You may direct telephone requests to the Chief Financial Officer at (214) 905-5100.

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#### CERTAIN INFORMATION WE ARE INCORPORATING BY REFERENCE

We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Securities and Exchange Act of 1934:

- \* Annual Report on Form 10-K for the fiscal year ended December 31, 1999;
- \* Registration Statement on Form 8-A filed on March 29, 2000;
- \* Quarterly Report on Form 10-Q for the quarter ended March 31, 2000;
- \* Quarterly Report on Form 10-Q for the quarter ended June 30, 2000;
- \* Quarterly Report on Form 10-Q for the quarter ended September 30, 2000;  
and
- \* The description of the common stock contained in Access' Registration Statement (No. 333-95413) filed with the SEC under Section 12(d) of the Securities Exchange Act including any amendment or report filed for the purpose of updating such description.

You may request a copy of these filings at no cost, by writing, telephoning or e-mailing us at the following address:

Access Pharmaceuticals, Inc.  
2600 Stemmons Freeway, Suite 176  
Dallas, Texas 75207  
Attention: Chief Financial Officer  
(214) 904-5100  
email: [axcs@accesspharma.com](mailto:axcs@accesspharma.com)

This prospectus is part of a Registration Statement we filed with the SEC. You should rely only on the information incorporated by reference or provided in this prospectus. No one else is authorized to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume



that the information in this prospectus is accurate as of any date other than the date on the front of this document.

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We have not authorized any dealer, salesperson or other person to give any information or to make any representations not contained in this Prospectus or any Prospectus Supplement. You must not rely on any unauthorized information. Neither this Prospectus nor any Prospectus Supplement is an offer to sell or a solicitation of an offer to buy any of these securities in any jurisdiction where an offer or solicitation is not permitted. No sale made pursuant to this Prospectus shall, under any circumstances, create any implication that there has not been any change in the affairs of Access since the date of this Prospectus.

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934,605 SHARES

[ LOGO ]

Access Pharmaceuticals, Inc.

COMMON STOCK

PROSPECTUS

\_\_\_\_\_, 2001

## PART II INFORMATION NOT REQUIRED IN PROSPECTUS

### Item 14. Other Expenses of Issuance and Distribution.

Estimated expenses (other than underwriting discounts and commissions) payable in connection with the sale of our common stock offer hereby are as follows:

SEC registration fee	\$ 1,450
Printing and engraving expenses	0
Legal fees and expenses	10,000

Accounting fees and expenses	5,000	
Blue Sky fees and expenses (including legal fees)		0
Transfer agent and registrar fees and expenses		0
Miscellaneous	1,550	
	-----	
Total		\$18,000

#### Item 15. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation Law (the "DGCL") empowers a Delaware corporation to indemnify any person who was or is, or is threatened to be made, a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation) by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, provided that such person acted in good faith and in a manner that such person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, such person had no reasonable cause to believe his conduct was unlawful. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding. A Delaware corporation may also indemnify such persons against expenses (including attorneys' fees) in actions brought by or in the right of the corporation to procure a judgment in its favor, subject to the same conditions set forth in the immediately preceding sentences, except that no indemnification is permitted in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and to the extent the Court of Chancery of the State of Delaware or the court in which such action or suit was brought shall determine upon application that, in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses as the Court of Chancery or other such court shall deem proper. To the extent such person has been successful on the merits or otherwise in defense of any action to above, or in defense of any claim, issue or matter therein, the corporation must indemnify such person against expenses (including attorneys' fees) actually and reasonably incurred by such person in connection therewith. The indemnification and advancement of expenses provided for in, or granted pursuant to, Section 145 is not exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any by-law, agreement, vote of stockholders or disinterested directors or otherwise.

Section 145 of the DGCL also provides that a corporation may maintain insurance against liabilities for which indemnification is not expressly provided by the statute. The Registrant is insured against liabilities which it may incur by reason of its indemnification obligations under its Certificate of Incorporation, Bylaws and indemnification agreements.

Article X of the Registrant's Certificate of

Incorporation provides that the Registrant will indemnify, defend and hold harmless directors, officers, employees and agents or the Registrant to the fullest extent currently permitted under the DGCL.

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In addition, Article X of the Registrant's Certificate of Incorporation, provides that neither the Registrant nor its stockholders may recover monetary damages from the Registrant's directors for a breach of their fiduciary duty in the performance of their duties as directors of the Registrant, unless such breach relates to (i) the director's duty of loyalty, (ii) acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL or (iv) any transactions for which the director derived an improper personal benefit. The By-Laws of the Registrant provide for indemnification of the Registrant's directors, officers, employees and agents on the terms permitted under Section 145 of the DGCL described above.

The Registrant has entered into indemnification agreements with certain of its directors and executive officers. These agreements provide rights of indemnification to the full extent allowed and provided for by Section 145 of the DGCL and the Certificate of Incorporation and Bylaws of Access.

## Item 16. Exhibits

### Exhibit Number

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

2.2 Agreement of Merger and Plan of Reorganization, dated May 23, 1997 among us, Access Holdings, Inc and Tacora Corporation (Incorporated by reference to Exhibit 10.11 of the Company's Form 10-K for the year ended December 31, 1997)

2.3 Agreement of Merger and Plan of Reorganization, dated as of February 23, 1999 among us, Access Holdings, Inc. and Virologix Corporation (Incorporated by reference to Exhibit 2.2 of the Company's Form 8-K filed on August 3, 1999)

### 3.0 Articles of incorporation and bylaws:

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

3.2 Certificate of Amendment of Certificate of Incorporation filed August 21, 1992  
3.3 Certificate of Merger filed January 25, 1996. (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)

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

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

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

ended December 31, 1996)

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

5.1 Opinion of Bingham Dana, LLP

23.0 Consent of Experts and Counsel

23.1 Consent of Bingham Dana LLP (included in Exhibit 5.1)

23.2 Consent of Grant Thornton LLP

23.3 Consent of KPMG LLP

23.4 Consent of Smith, Anglin & Co.

26 Power of Attorney (For information, see II-4)

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Item 17. Undertakings.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made pursuant to this Registration Statement, a post-effective amendment to this Registration Statement to include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new Registration Statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions described in Item 15 above, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses

incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Dallas, Texas, on this 16th day of January, 2001.

ACCESS PHARMACEUTICALS, INC.

By /s/ Kerry P. Gray

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

Pursuant to the requirements of the Securities Act of 1933, the Registration Statement has been signed by the following person in the capacities and on the dates indicated.

<TABLE>  
<CAPTION>

Signature	Title	Date
----- <S> /s/ Kerry P. Gray ----- Kerry P. Gray	<C> President and Chief Executive Officer, Director	<C> January 16, 2001
* ----- Herbert H. McDade, Jr.	Director	January 16, 2001
* ----- J. Michael Flinn	Director	January 16, 2001
* ----- Stephen B. Howell	Director	January 16, 2001
* ----- Max Link	Director	January 16, 2001
* ----- Richard Stone	Director	January 16, 2001
* ----- Preston Tsao	Director	January 16, 2001

/s/ Stephen B. Thompson

-----  
Stephen B. Thompson Vice President,  
Chief Financial Officer, January 16, 2001  
Treasurer

\* By: /s/ Kerry P. Gray

-----  
Attorney In Fact

</TABLE>

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EXHIBIT 5.1

Opinion of Bingham Dana LLP

Bingham Dana LLP  
150 Federal Street  
Boston, MA 02110

January 16, 2001

Access Pharmaceuticals, Inc.  
2600 Stemmons Freeway, Suite 176  
Dallas, Texas 75207

Re: Registration Statement on Form S-3

Ladies and Gentlemen:

This opinion is furnished in connection with the registration, pursuant to a Registration Statement on Form S-3 under the Securities Act of 1933, as amended (the "Act"), initially filed with the Securities and Exchange Commission on January 16, 2001 (the "Registration Statement"), of up to 902,701 shares (the "Shares") of common stock, par value \$0.01 per share (the "Common Stock"), of Access Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and 31,904 shares of Common Stock issuable upon exercise of currently outstanding warrants to purchase Common Stock (the "Warrant Shares"), to be sold by certain selling stockholders of the Company.

We have acted as counsel to the Company in connection with the foregoing registration of the Shares. We have examined and relied upon originals or copies of such records, instruments, agreements or other documents of the Company, and certificates of officers of the Company as to certain factual matters and have made such investigation of law and have discussed with officers and representatives of the Company such questions of fact, as we have deemed necessary or advisable for purposes of this opinion. In our examinations, we have assumed the genuineness of all signatures, the conformity to the originals of all documents reviewed by us as copies, the authenticity and completeness of all original documents reviewed by us in original or copy form and the legal competence of each individual executing any document.

We have further assumed that the registration requirements of the Act and all applicable requirements of state laws regulating the sale of securities will have been duly satisfied.

This opinion is limited solely to the Delaware General Corporation Law, as applied by courts located in Delaware, the applicable provisions of the Delaware Constitution and the reported judicial decisions interpreting those laws.

Based upon and subject to the foregoing, we are of the opinion that the Shares are legally issued, fully paid and non-assessable and that the Warrant Shares, when issued upon the due exercise of and in accordance with the terms of the warrants under which such Warrant Shares are issuable, will be legally issued, fully paid and non-assessable.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the reference to this firm under the heading "Legal Matters" in the Registration Statement.

Very truly yours,

/s/ Bingham Dana LLP

BINGHAM DANA LLP





EXHIBIT 23.2

Consent Of Independent Certified Public Accountants

We have issued our report dated March 3, 2000 accompanying the consolidated financial statements of Access Pharmaceuticals, Inc. and subsidiaries appearing in the 1999 Annual Report of the Company on Form 10-K for the year ended December 31, 1999, which is incorporated by reference in this Registration Statement. We consent to the incorporation by reference in the Registration Statement of the aforementioned report and to the use of our name as it appears under the caption "Experts."

/s/ Grant Thornton LLP

GRANT THORNTON LLP

Dallas, Texas  
January 12, 2001

EXHIBIT 23.3

Independent Auditors' Consent

The Board of Directors of  
Access Pharmaceuticals, Inc.

We consent to the use of our report incorporated herein by reference and to the reference to our firm under the heading "Experts" in the prospectus.

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

/s/ KPMG LLP

KPMG LLP

Dallas, Texas  
January 16, 2001

EXHIBIT 23.4

Consent of Independent Auditors

We consent to the use of our report, dated September 21, 1995, incorporated herein by reference and to the reference to our firm under the heading "Experts" in the prospectus.

/s/ Smith Anglin & Co.

Smith Anglin & Co.

Dallas, Texas  
January 16, 2001