
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**AMENDMENT NO. 1
TO**

**FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933**

ACCESS PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

3841
(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)

**Stephen B. Thompson
Chief Financial 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 a copy to:
**John J. Concannon III, Esq.
Bingham McCutchen LLP
150 Federal Street
Boston, MA 02110
(617) 951-8000**

**Approximate date of commencement of proposed sale to public:
As soon as practicable after the effective date hereof.**

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, check the following box.

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

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration 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 Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Security(1)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common stock, \$0.01 par value per share	7,649,823(2)	\$ 2.28	\$ 17,441,596.44	0(3)

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933. For the purposes of this table, we have used the average of the high and low prices reported in the consolidated reporting system of the American Stock Exchange on May 25, 2005.

(2) Of these shares, 6,741,573 shares are being registered under the Standby Equity Distribution Agreement, 196,500 shares are being registered as a commitment fee to Cornell Capital Partners under the Standby Equity Distribution Agreement, 3,500 shares are being registered as a placement agent fee to Newbridge Securities Corporation, 658,250 shares are being registered under the registrant's 7% Secured Convertible Debentures due March 30, 2006, 50,000 shares were issued to the holders of the 7% Secured Convertible Debentures.

(3) \$2,052.88 was previously paid to the Commission with the initial filing of this registration statement on May 27, 2005.

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.

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INFORMATION CONTAINED HEREIN 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 IN ANY STATE IN WHICH AN OFFER, SOLICITATION, OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED JUNE 10, 2005

PROSPECTUS

ACCESS PHARMACEUTICALS, INC.

7,649,823 Shares of Common Stock

This Prospectus relates to the offer and sale of up to 7,649,823 shares of common stock, \$0.01 par value per share, of Access Pharmaceuticals, Inc. ("Access") by certain persons who are stockholders of Access, including Cornell Capital Partners, LP ("Cornell Capital Partners"), Highgate House Funds, Ltd., and Newbridge Securities Corporation. Please refer to the "Selling Stockholders" beginning on page 18.

Access is not selling any shares of common stock in this offering and therefore will not receive any of the proceeds from this offering. Access will, however, receive proceeds from the sale of common stock under the Standby Equity Distribution Agreement (the "Standby Equity Distribution Agreement"), which was entered into as of March 30, 2005 with Cornell Capital Partners and no other stockholders. All costs associated with this registration will be borne by Access.

The shares of common stock are being offered for sale by the selling stockholders at prices established on the American Stock Exchange ("AMEX") during the term of this offering. On May 25, 2005, the last reported sale price of our common stock was \$2.35 per share. Our common stock is presently listed on AMEX under the symbol "AKC". These prices will fluctuate based on the demand for the shares of common stock.

The Selling Stockholders consist of: (i) Cornell Capital Partners, which intends to sell up to 7,292,198 shares of common stock, 6,741,573 of which shares are under the Standby Equity Distribution, 146,500 of which shares were issued as a commitment fee, 50,000 of which shares may be issued as a commitment fee, 329,125 of which shares are under Access' 7% Secured Convertible Debentures due March 30, 2006 (the "Secured Convertible Debentures"), and 25,000 of which shares were issued in connection with the issuance of the Secured Convertible Debentures, (ii) Newbridge Securities Corporation, which intends to sell up to 3,500 shares of common stock that were issued to it as a placement agent fee, and (iii) Highgate House Funds, Ltd., which intends to sell up to 354,125 shares of common stock, 329,125 of which shares are under the Secured Convertible Debentures, and 25,000 of which shares were issued in connection with the issuance of the Secured Convertible Debentures. We will issue Cornell Capital Partners 50,000 shares of our common stock within ten business days of the date that we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement.

Cornell Capital Partners is an "underwriter" within the meaning of the Securities Act of 1933 in connection with the sale of common stock under the Standby Equity Distribution Agreement. Cornell Capital Partners will pay Access 98% of, or a 2% discount to, the lowest daily volume weighted average price ("VWAP") of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. In addition, Cornell Capital Partners will retain 3.5% of each advance under the Standby Equity Distribution Agreement. Cornell Capital Partners also received a one-time commitment fee in the form of 146,500 shares of common stock. We will issue Cornell Capital Partners 50,000 shares of our common stock within ten business days of the date that we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement. The 2% discount, the 3.5% retainage fee and the 196,500 compensation shares are underwriting discounts payable to Cornell Capital Partners.

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Access engaged Newbridge Securities Corporation, an unaffiliated registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. Newbridge Securities Corporation was paid a fee of 3,500 shares of Access' common stock on March 30, 2005, under a Placement Agent Agreement.

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state law or that an exemption from registration is available.

With the exception of Cornell Capital Partners, which is an "underwriter" within the meaning of the Securities Act of 1933, no other underwriter or person has been engaged to facilitate the sale of shares of common stock in this offering. This offering will terminate twenty-four months after the accompanying registration statement is declared effective by the Securities and Exchange Commission. None of the proceeds from the sale of stock by the selling stockholders will be placed in escrow, trust or any similar account.

**These securities are speculative and involve a high degree of risk.
You should purchase securities only if you can afford a complete loss of your investment.**

See "Risk factors" beginning on page 5.

These securities have not been approved or disapproved by the Securities and Exchange Commission or any state securities commission nor has the Securities and Exchange Commission or any state securities commission passed upon the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offense.

THE DATE OF THIS PROSPECTUS IS _____, 2005.

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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 OUR AFFAIRS SINCE THE DATE OF THIS PROSPECTUS.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this Prospectus. This summary does not contain all the information you should consider before investing in shares of our common stock. You should read this entire Prospectus carefully, including “Risk Factors” beginning on page 5 and our financial statements and the notes to those financial statements beginning on F-1 before making an investment decision.

ABOUT ACCESS

Company Overview

We are an emerging pharmaceutical company focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities.

Together with our subsidiaries, we have proprietary patents or rights to seven drug delivery technology platforms:

- synthetic polymer targeted delivery,
- vitamin mediated targeted delivery
- vitamin mediated oral delivery,
- bioerodible cross-linker technology,
- mucoadhesive disc technology,
- hydrogel particle aggregate technology, and
- Residerm® topical delivery.

In addition, we have acquired the amlexanox patents and technology for the treatment of mucosal and skin disorders.

We use our proprietary technology to develop products and product candidates. Our patents and trade secrets protect our marketed products, amlexanox 5% paste (marketed under the trade names Aphthasol® and Aptheal®) and Zindaclin®, and our product candidates that are currently in the drug development phase, DACH platinum (AP 5346), polymer platinate (AP 5280) and OraDisc™.

We are marketing amlexanox 5% paste, the first U.S. Food and Drug Administration (FDA) approved product for the treatment of canker sores, under the trade name Aphthasol® in the United States. In September 2001, ProStrakan Limited, our United Kingdom partner, received marketing authorization to market amlexanox 5% paste in the U. K. under the trade name Aptheal®. We have received marketing approval in 10 European Union countries following completion of the Mutual Recognition Procedure (MRP). Approval to market was granted in Austria, Germany, Greece, Finland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, and Sweden. We are developing new formulations and delivery forms of amlexanox, including mucoadhesive disc delivery. In 2004, we received approval of our new drug application for OraDisc™ A from the United States Food and Drug Administration (“FDA”). OraDisc™ A is an improved delivery system for amlexanox. The OraDisc™ technology is a proprietary mucoadhesive patch that gradually erodes and releases an active ingredient when applied to the inside of the mouth.

In addition, ProStrakan has used our patented Residerm® technology to develop a zinc clindamycin formulation for the treatment of acne. ProStrakan began marketing zinc clindamycin in the United Kingdom under the trade name Zindaclin® in March 2002. The process to achieve marketing authorization for Zindaclin® throughout Europe has now been completed, with approvals in most European Union countries including the new member states and several non-European countries. We anticipate that in the next twelve months approvals will be obtained in additional other countries.

On May 11, 2005, we announced that Kerry P. Gray resigned as our President and Chief Executive Officer, effective as of May 10, 2005. Mr. Gray resigned from our Board of Directors and from all other positions held with us, effective as of May 10, 2005. We entered into a Separation Agreement with Mr. Gray dated as of May 10, 2005. Pursuant to the terms of the Separation Agreement, Mr. Gray has agreed to provide us with certain post-termination assistance. He also agreed to maintain the confidentiality of our proprietary information and to a customary mutual release of claims with us. The Separation Agreement provides for an immediate cash payment to Mr. Gray of \$225,000 and payments of \$33,333.33 each month for a period of 18 months, which payments are secured by a lien

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on our assets. We are required to issue 3,500 shares of our common stock to Mr. Gray each month for a period of 18 months following May 10, 2005. The Separation Agreement also provides that all of Mr. Gray's outstanding stock options and shares of restricted stock immediately and fully vested and options remain exercisable for a period of two years.

On May 11, 2005, we announced that Rosemary Mazanet, M.D., Ph.D, has been named by the Board of Directors as our Acting Chief Executive Officer, effective as of May 11, 2005. The agreement is memorialized in a Letter Agreement with us, dated May 10, 2005. Dr. Mazanet's title will be Acting Chief Executive Officer and she will report directly to, and be subject to the direction of, our Board of Directors. Dr. Mazanet will be paid a weekly salary of \$7,500 for the duration of the Letter Agreement, and she was granted a non-qualified stock option of 30,000 shares of our common stock, with an exercise price equal to the last sale price on May 10, 2005. Dr. Mazanet's option will vest monthly over a six month period. The Letter Agreement also grants Dr. Mazanet similar employee benefits as our other executive officers, D&O insurance coverage and a signing bonus of \$30,000. The Letter Agreement provides for additional option or cash grants based on milestones to be agreed upon by Dr. Mazanet and our Board of Directors.

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

SUMMARY OF THE OFFERING

This offering relates to the sale of common stock by certain persons who are the selling stockholders consisting of (i) Cornell Capital Partners, which intends to sell up to 7,292,198 shares of common stock, 6,741,573 of which shares are under the Standby Equity Distribution, 146,500 of which shares were issued as a commitment fee, 50,000 of which shares may be issued as a commitment fee, 329,125 of which shares are under the Secured Convertible Debentures, and 25,000 of which shares were issued in connection with the issuance of the Secured Convertible Debentures, (ii) Newbridge Securities Corporation, which intends to sell up to 3,500 shares of common stock that were issued to it as a placement agent fee, and (iii) Highgate House Funds, Ltd., which intends to sell up to 354,125 shares of common stock, 329,125 of which shares are under the Secured Convertible Debentures, and 25,000 of which shares were issued in connection with the issuance of the Secured Convertible Debentures.

Pursuant to the Standby Equity Distribution Agreement, we may, at our discretion, periodically issue and sell to Cornell Capital Partners shares of common stock for a total purchase price of \$15.0 million. The amount of each advance is subject to a maximum advance amount of \$1,000,000, and we may not submit any advance within five trading days of a prior advance. Cornell Capital Partners will pay us 98% of, or a 2% discount to, the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. Of each advance made by us, Cornell Capital Partners shall retain 3.5% of each advance. Cornell Capital Partners also received a one-time commitment fee in the form of 146,500 shares of common stock. We will issue Cornell Capital Partners 50,000 shares of our common stock within ten business days of the date that we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement. We understand that Cornell Capital Partners intends to sell any shares purchased under the Standby Equity Distribution Agreement at the then prevailing market price. Among other things, this Prospectus relates to the shares of common stock to be issued under the Standby Equity Distribution Agreement. There are substantial risks to investors as a result of the issuance of shares of common stock under the Standby Equity Distribution Agreement. These risks include dilution of shareholders, significant decline in our stock price and our inability to draw sufficient funds when needed.

There is an inverse relationship between our stock price and the number of shares to be issued under the Standby Equity Distribution Agreement. That is, as our stock price declines, we would be required to issue a greater number of shares under the Standby Equity Distribution Agreement for a given advance. This inverse relationship is demonstrated by the following tables, which show the net cash to be received by us and the number of shares to be

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issued under the Standby Equity Distribution Agreement at a recent price of \$2.27 per share and 25%, 50% and 75% discounts to the recent price.

Market Price:	\$ 2.27	\$ 1.70	\$ 1.14	\$ 0.57
Purchase Price:	\$ 2.225	\$ 1.67	\$ 1.11	\$ 0.56
No. of Shares (1):	6,741,573	6,741,573	6,741,573	6,741,573
Total Outstanding (2):	21,781,057	21,781,057	21,781,057	21,781,057
Percent Outstanding (3):	30.95%	30.95%	30.95%	30.95%
Net Cash to Access (4):	14,426,000	14,426,000	14,426,000	14,426,000

- (1) Represents the number of shares of common stock which could be issued to Cornell Capital Partners under the Standby Equity Distribution Agreement at the prices set forth in the table.
- (2) Represents the total number of shares of common stock outstanding after the issuance of the shares to Cornell Capital Partners under the Standby Equity Distribution Agreement, not including shares issued under the convertible debentures.
- (3) Represents the shares of common stock to be issued as a percentage of the total number shares outstanding.
- (4) Net cash equals the gross proceeds minus the 3.5% retainage and \$49,053 in offering expenses.

We are registering 658,250 shares of common stock under this Prospectus under the Secured Convertible Debentures. Pursuant to a Securities Purchase Agreement, we issued the Secured Convertible Debentures to Cornell Capital Partners and Highgate House Funds, Ltd. in the aggregate original principal amount of \$2,633,000. The debentures are convertible at the holders' option at any time up to maturity at the fixed conversion price of \$4.00. If the full amount of the Secured Convertible Debentures or \$2,633,000 is converted into shares of our common stock, up to 685,250 shares of common stock will be issued to the holders of the Secured Convertible Debentures at any time up to the maturity date of the Secured Convertible Debentures on March 30, 2006. However, this does not take into account the 4.99% ownership limitation under the Secured Convertible Debentures. Assuming the holders of the Secured Convertible Debentures had converted the \$2,633,000 in Secured Convertible Debentures into 685,250 shares of common stock at a fixed price of \$4.00 on December 31, 2004, this would represent an immediate dilution to any new stockholders of \$0.68 per share. The Secured Convertible Debentures are secured by all of our assets and, in addition, we could be required to issue and the holders would have the ability to sell up to 2,891,723 shares of our common stock. The Secured Convertible Debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005, to the extent that the Secured Convertible Debentures have not been converted to shares of our common stock. We have the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, we issued to the holders an aggregate of 50,000 shares of our common stock.

We engaged Newbridge Securities Corporation, an unaffiliated registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. Newbridge Securities Corporation was paid a fee of 3,500 shares of our common stock on March 30, 2005, under a Placement Agent Agreement.

Common Stock Offered	7,649,823 shares by the selling stockholders
Offering Price	Market Price
Common Stock Outstanding Before the Offering	15,724,734 shares as of May 9, 2005
Use of Proceeds	We will not receive any proceeds of the shares offered by the selling stockholders. Any proceeds we receive from the sale of common stock under the Standby Equity Distribution Agreement will be used for general working capital purposes. See "Use of Proceeds."

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Risk Factors

The securities offered hereby involve a high degree of risk and immediate substantial dilution. See "Risk Factors" and "Dilution."

AMEX Symbol

AKC

SUMMARY CONDENSED CONSOLIDATED FINANCIAL INFORMATION

The following summary condensed consolidated financial information as of and for the years ended December 31, 2004, 2003, 2002, 2001 and 2000 have been derived from our audited financial statements. The financial information as of and for the three months ended March 31, 2005 and 2004 is derived from our unaudited consolidated financial statements. The summary condensed consolidated financial information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and notes thereto included elsewhere in this Prospectus.

	<u>For the Three Months</u>		<u>For the Year Ended December 31,</u>				
	<u>Ended</u>		2004	2003	2002	2001	2000
	2005	2004	2004	2003	2002	2001	2000
	<u>March 31,</u>						
	<u>(in thousands, except amounts per share)</u>						
Consolidated Statement of Operations and Comprehensive Loss Data:							
Total revenues	\$ 155	\$ 20	\$ 549	\$ 1,295	\$ 1,147	\$ 243	\$ 107
Operating loss	(2,119)	(2,064)	(9,079)	(8,213)	(8,700)	(6,308)	(6,058)
Interest and miscellaneous income	10	33	226	2,559	594	1,451	972
Interest and other expense	(313)	(320)	1,385	1,281	1,278	1,170	342
Net loss	(2,422)	(2,351)	(10,238)	(6,935)	(9,384)	(6,027)	(5,428)
Common Stock Data:							
Net loss per basic and diluted common share	\$ (.16)	\$ (.17)	\$ (0.68)	\$ (0.52)	\$ (0.72)	\$ (0.47)	\$ (0.49)
Weighted average basic and diluted common shares outstanding	15,525	14,200	15,162	13,267	13,104	12,857	11,042

	<u>For the Three Months</u>		<u>For the Year Ended December 31,</u>				
	<u>Ended</u>		2004	2003	2002	2001	2000
	2005	2004	2004	2003	2002	2001	2000
	<u>March 31,</u>						
	<u>(in thousands, except amounts per share)</u>						
Consolidated Balance Sheet Data:							
Cash, cash equivalents and short term investments	\$ 3,360	\$ 9,295	\$ 2,261	\$ 2,587	\$ 9,776	\$20,126	\$25,809
Restricted cash	398	619	1,284	649	468	600	—
Total assets	11,761	18,496	11,090	11,811	19,487	25,487	30,526
Deferred revenues	1,428	1,180	1,199	1,184	1,199	508	551
Convertible notes	16,163	13,530	13,530	13,530	13,530	13,530	13,530
Total liabilities	20,320	17,543	17,751	17,636	18,998	16,409	15,522
Total stockholders' equity (deficit)	(8,559)	(953)	(6,661)	(5,825)	489	9,078	15,004

RISK FACTORS

Any investment in our securities involves a high degree of risk. You should carefully consider the risks described below, which we believe are all the material risks to our business, together with the information contained elsewhere in this Prospectus, before you make a decision to invest in our company.

RISKS RELATED TO OUR BUSINESS

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 \$66.9 million through March 31, 2005. Losses for the years ended 2004, 2003 and 2002 were \$10,238,000, \$6,935,000 and \$9,384,000, respectively. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop clinical drug candidates and from the associated administrative costs. We expect to incur additional operating losses over the next several years. We also expect cumulative losses to increase due to expanded research and development efforts and preclinical and clinical trials. Our net cash burn rate for the past twelve months was approximately \$750,000 per month. We project our net cash burn rate for the next twelve months to be approximately \$600,000 per month. Capital expenditures are forecasted to be minor for the next twelve months since most of our new equipment is leased and the lease expense is included in the calculation of the net cash burn rate.

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

To date, we have funded our operations primarily through private sales of common stock and convertible notes. Contract research payments and licensing fees from corporate alliances and mergers have also provided funding for our operations. 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 amlexanox, Zindaclin® or OraDisc™ products to date and we may not generate 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, obtain required regulatory approvals and market any additional products. Moreover, even if we do identify, develop, commercialize, patent, manufacture, and obtain required regulatory approvals to market additional products, we may not generate 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 minimal product sales and royalties, any amounts that we receive under strategic partnerships and research or drug development collaborations that we may establish and, as a result, we may be unable to achieve or maintain profitability in the future or to achieve significant revenues in order to fund our operations.

A failure to obtain necessary additional capital in the future could jeopardize our operations.

We have issued an aggregate of \$13,530,000 of convertible notes, which are due in two parts — \$8,030,000 is due on September 13, 2005 and \$5,500,000 is due on September 13, 2008. The notes may convert to common stock at a conversion price of \$5.50 and we can redeem the notes for the principal amount of the notes plus interest if our common stock trades above a price of \$8.25 for any period of ten consecutive trading days prior to our notice of redemption. In addition, on March 30, 2005 we issued \$2,633,000 of the Secured Convertible Debentures, which convert at \$4.00 per share. We do not have sufficient funds to repay our convertible notes at their maturity. We may not be able to restructure the convertible notes or obtain additional financing to repay them on terms acceptable to us, if at all. If we raise additional funds by selling equity securities including in connection with our Standby Equity Distribution Agreement with Cornell Capital Partners, the relative equity ownership of our existing investors would be diluted and the new investors could obtain terms more favorable than previous investors. A failure to restructure our convertible notes or obtain additional funding to repay the convertible notes and support our working capital and operating requirements, could cause us to be in default of our convertible notes and prevent us from making expenditures that are needed to allow us to maintain our operations.

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Our financial condition and the restrictive covenants contained in our outstanding convertible notes may limit our ability to borrow additional funds or to raise additional equity as may be required to fund our future operations.

We incurred significant losses from operations of \$2.4 million for the quarterly period ended March 31, 2005, \$2.4 million for the quarterly period ended March 31, 2004, \$9.1 million for the year ended December 31, 2004 and \$8.2 million for the year ended December 31, 2003. Moreover, the terms of our outstanding convertible notes may limit our ability to, among other things:

- incur additional debt;
- retire, exchange or amend the terms of outstanding debt;
- pay cash dividends, redeem, retire or repurchase our stock or change our capital structure;
- enter into certain transactions with affiliates;
- create additional liens on our assets;
- issue certain types of preferred stock or issue common stock at below market prices; or
- merge or consolidate with other entities.

Our ability to borrow additional funds or raise additional equity may be limited by our financial condition, in addition to the terms of our outstanding debt. Additionally, events such as our inability to continue to reduce our loss from continuing operations, could adversely affect our liquidity and our ability to attract additional funding as required.

We may not be able to pay our debt and other obligations and our assets may be seized as a result.

We may not generate the cash flow required to pay our liabilities as they become due. Our outstanding debt includes approximately \$8.03 million of our Convertible Subordinated Notes due in September 2005, \$5.5 million of our Convertible Subordinated Notes due in September 2008 and \$2,633,000 of our Secured Convertible Debentures due in March 2006.

We may be unable to repay or repurchase the Secured Convertible Debentures due in March 2006 and convertible subordinated notes due in September 2005 and September 2008 upon a repurchase event and be forced into bankruptcy.

The holders of our Convertible Notes may require us to repurchase or prepay all of the outstanding Convertible Notes under certain circumstances. We may not have sufficient cash reserves to repurchase the Convertible Notes at such time, which would cause an event of default under the Convertible Notes and may force us to declare bankruptcy.

Our obligations under the secured convertible notes are secured by all of our assets

Our obligations under the Secured Convertible Debentures are secured by all of our assets. As a result, if we default under the terms of the Secured Convertible Debentures or related agreements, including our failure to issue shares of common stock upon conversion by the holder, our failure to timely file a registration statement or have such registration statement declared effective, breach of any covenant, representation or warranty in the Securities Purchase Agreement or related Secured Convertible Debentures or the commencement of a bankruptcy, insolvency,

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reorganization or liquidation proceeding against us could require the early repayment of the Secured Convertible Debentures, if the default is not cured with the specified grace period. In addition we could be required to issue and the holders would have the ability to sell up to 2,891,723 shares of our common stock and/or the holders could foreclose their security interest and liquidate some or all of our assets and we could cease to operate. Any such issuance of shares could cause a significant drop in the price of our stock and significant dilution to our stockholders.

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 and our failure to develop safe, commercially viable drugs would severely limit our ability to become profitable or to achieve significant revenues. We may be unable to successfully commercialize our drug candidates for a number of reasons, including:

- some or all of our drug candidates may be found to be unsafe or ineffective or otherwise fail to meet applicable regulatory standards or receive necessary regulatory clearances;
- our drug candidates, if safe and effective, may be too difficult to develop into commercially viable drugs;
- it may be difficult to manufacture or market our drug candidates on a large scale;
- proprietary rights of third parties may preclude us from marketing our drug candidates; and
- third parties may market superior or equivalent drugs.

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

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

We require substantial capital for our development programs and operating expenses, to pursue regulatory clearances and to prosecute and defend our intellectual property rights. We believe that our existing capital resources, interest income, product sales, royalties and revenue from possible licensing agreements and collaborative agreements will be sufficient to fund our currently expected operating expenses (other than debt obligations including the \$8,030,000 of convertible notes that are required to be repaid in September 2005 and \$2,633,000 of the Secured Convertible Debentures due in March 2006) and capital requirements through March 2006. However, unless our convertible notes convert to common stock prior to their maturity or are restructured, we will need to raise substantial additional capital to support our ongoing operations and debt obligations because our convertible notes will mature and/or our actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including:

- the sales levels of our marketed products;
- the results of our research and development programs;
- the timing and results of preclinical and clinical trials;
- our ability to maintain existing and establish new collaborative agreements with other companies to provide funding to us;
- technological advances; and
- activities of competitors and other factors.

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If we do raise additional funds by issuing equity securities, further dilution to existing stockholders would result and future investors may be granted rights superior to those of our 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.

We may be unable to successfully develop, market, or commercialize our products or our product candidates without establishing new relationships and maintaining current relationships.

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, we may seek to joint venture, sublicense or enter 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 such additional collaborative arrangements, license agreements, or marketing agreements as we may deem necessary to develop, commercialize and market our potential pharmaceutical products on acceptable terms. Furthermore, if we maintain and establish arrangements or relationships with third parties, our business may depend upon the successful performance by these third parties of their responsibilities under those arrangements and relationships. For our commercialized products we currently rely upon the following relationships in the following marketing territories for sales, manufacturing or regulatory approval efforts:

- amlexanox 5% paste and OraDisc™ A
 - o Discus Dental, Inc. – United States marketing rights
 - o ProStrakan Ltd. — United Kingdom and Ireland manufacturing, marketing rights and regulatory approval
 - o Zambon Group — France, Germany, Holland, Belgium, Luxembourg, Switzerland, Brazil, Colombia and Italy manufacturing and marketing rights
 - o Laboratories Dr. Esteve SA – Spain, Portugal and Greece manufacturing and marketing rights
 - o Meda, AB for Scandinavia, the Baltic states and Iceland marketing rights
 - o Mipharm SpA for Italy manufacturing and marketing rights
 - o Paladin Labs, Inc. for Canada manufacturing and marketing rights
 - o EpiTan, Ltd. for Australia and New Zealand for marketing rights
 - o Orient Europharma, Co., Ltd. for Taiwan, Hong-Kong, Malaysia, Philippines, Thailand and Singapore for marketing rights
- Zindaclin® and Residerm®
 - o ProStrakan Ltd. – worldwide manufacturing, marketing and regulatory approval rights
 - o Fujisawa GmbH – sublicensed continental Europe marketing rights
 - o EpiTan, Ltd. – sublicensed Australia and New Zealand marketing rights
 - o Hyundai – sublicensed Korea marketing rights
 - o Taro – sublicensed Israel marketing rights
 - o Biosintetica – sublicensed Brazil marketing rights
 - o Pliva dd Hrvatska d.o.o. – sublicensed Czech, Estonia, Hungary, Latvia, Poland, Slovak and Slovenia marketing rights
 - o Five companies for five other smaller countries - sublicensed marketing rights

For one of our OraDisc™ products in development, on January 6, 2004, we entered into an exclusive license and supply agreement with Wyeth Consumer Healthcare for sales of the product in North America. If this product is marketed, we will be dependent upon Wyeth Consumer Healthcare for sales of such product in this territory.

Our ability to successfully commercialize, and market our products and product candidates could be limited if a number of these existing relationships were terminated.

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Furthermore, our strategy with respect to our polymer platinate program is to enter into a licensing agreement with a pharmaceutical company pursuant to which the further costs of developing a product would be shared with our licensing partner. Although we have had discussions with potential licensing partners with respect to our polymer platinate program, to date we have not entered into any licensing arrangement. We may be unable to execute our licensing strategy for polymer platinate.

We may be unable to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes without the assistance of contract manufacturers, which may be difficult for us to obtain and maintain.

We have limited 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. As a result, we have established, and in the future 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 clinical programs and submission of product candidates for regulatory approval, which could cause our business to suffer. Our business could suffer if there are 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 or subsequent sales of such products. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by the FDA. In this regard, the FDA will not issue a pre-market approval or product and establishment licenses, where applicable, to a manufacturing facility for the products until 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 ability to generate profits or acceptable profit margins and our ability to develop and deliver such products on a timely and competitive basis.

Our amlexanox 5% paste is marketed in the US as Aphthasol®. We selected Contract Pharmaceuticals Ltd. Canada as our new manufacturer of amlexanox 5% paste and they manufacture product for the US market and initial qualifying batches of the product for Europe. We re-launched Aphthasol® in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004 and in the quarter ended March 31, 2005.

Amlexanox 5% paste was approved by regulatory authorities for sale in the UK. Approval to market was granted in Austria, Germany, Greece, Finland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, and Sweden. We did not receive approvals for France, Italy and Belgium. We licensed manufacturing rights to ProStrakan, Zambon, Esteve and Mipharm for specific countries in Europe. Contract Pharmaceuticals Ltd. Canada has also been selected as our European supplier of amlexanox 5% paste and this facility has been approved for European supply.

We licensed our patents for worldwide manufacturing and marketing for Zindaclin® and our ResiDerm® technology to ProStrakan Ltd. for the period of the patents. We receive a share of the licensing revenues and royalty on the sales of the product. ProStrakan has a contract manufacturer for Zindaclin® which is a European Union approved facility. Zindaclin® is approved in the UK and throughout Europe in most European Union countries including new member states and several non-European markets. Zindaclin® is marketed in the UK, France, Germany, Ireland, Belgium, Cyprus, Israel and Korea. Zindaclin® is under regulatory review in other markets including Australia, New Zealand, Brazil and others.

We received regulatory approval from the FDA to manufacture and sell OraDisc™ A in September 2004 and are proceeding with our manufacturing and marketing plans for 2005.

AP5346 is manufactured by third parties for our Phase I/II clinical trials. Manufacturing is ongoing for the current clinical trials. Certain manufacturing steps are conducted by us to enable significant cost savings to be realized.

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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 drugs and drug candidates require receipt and maintenance of governmental approvals for commercialization. Preclinical and clinical trials and manufacturing of our drug candidates are 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. The status of our principal products is as follows:

- 5% amlexanox paste is an approved product for sale in the US (Aphthasol®); approved in the UK and Canada but not yet sold; approved in ten EU countries but not yet sold;
- Zindaclin® is an approved product for sale in the UK and extensively throughout European Union countries; and is in the approval process in other markets.
- OraDisc™ A is an approved product for sale in the US as of September 2004; we are completing steps for manufacturing and sale of the product in 2005.
- Our other OraDisc™ products are currently in the pre-clinical phase.
- AP5346 has completed a Phase I clinical trial in Europe and has been approved for the commencement of a Phase I trial in the US by the FDA.
- Mucoadhesive liquid technology patient recruitment in the clinical trial is on hold pending commercial developments.
- Vitamin mediated delivery technology is currently in the pre-clinical phase.
- We also have other products in the preclinical phase.

Due to the time consuming and uncertain nature of the drug candidate development process and the governmental approval process described above, we cannot assure investors 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. Our drug candidates may not receive FDA or other regulatory approvals 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, 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. Preclinical or clinical trials of any of our future drug candidates may not 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 that may delay ultimate FDA approval or even lead us to terminate our efforts to develop the drug for commercial use. Like other companies in the biotechnology industry, we have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials. In particular, OraDisc™ and polymer platinate have taken longer to progress

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through clinical trials than originally planned. This extra time has not been related to concerns of the formulations but rather due to the lengthy regulatory process. 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. A delay or failure to receive regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in our attempts to further develop such candidates and obtain future regulatory approval.

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

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. These risks will expand with respect to our drug candidates, if any, that receive regulatory approval for commercial sale and we may face substantial liability for damages in the event of adverse side effects or product defects identified with any of our products that are used in clinical tests or marketed to the public. We generally procure product liability insurance for drug candidates that are undergoing human clinical trials. Product liability insurance for the biotechnology industry is generally expensive, if available at all, and as a result, we may be unable to obtain insurance coverage at acceptable costs or in a sufficient amount in the future, 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 that 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.

The following products may compete with polymer platinite:

- Cisplatin, marketed by Bristol-Myers-Squibb, the originator of the drug, and several generic manufacturers;
- Carboplatin, marketed by Bristol-Myers-Squibb, the originator of the drug and several generic manufacturers; and
- Oxaliplatin, marketed exclusively by Sanofi-Synthelabo.

The following companies are working on therapies and formulations that may be competitive with our polymer platinite:

- Antigenics and Regulon are developing liposomal formulations; and
- American Pharmaceutical Partners, Cell Therapeutics, Daiichi, Enzon and DebioPharm are developing alternate drugs in combination with polymers and other drug delivery systems.

The following products may compete with Residerm® products:

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- Benzamycin, marketed by a subsidiary of Aventis;
- Cleocin-T and a generic topical clindamycin, marketed by Pfizer;
- Benzac, marketed by Galderma; and
- Triaz, marketed by Medicis Pharmaceutical Corp.

Technology and prescription steroids such as Kenalog in OraBase, developed by Bristol-Myers Squibb, may compete with our commercialized Aphthasol® product. Over-the-counter (“OTC”) products including Orajel – Del Laboratories and Anbesol – Wyeth Consumer Healthcare also compete in the aphthous ulcer market.

Companies working on therapies and formulations that may be competitive with our vitamin mediated drug delivery system include Bristol-Myers-Squibb, Centocor (acquired by Johnson & Johnson), GlaxoSmithKline, Imclone and Xoma which are developing targeted monoclonal antibody therapy.

Amgen, CuraGen, McNeil, MGI Pharma and OSI Pharmaceuticals are developing products to treat mucositis that may compete with our mucoadhesive liquid technology.

BioDelivery, Biovail Corporation, Cellgate, CIMA Labs, Inc., Depomed Inc., Emisphere Technologies, Inc., Eurand, Flamel Technologies, Nobex and Xenoport are developing products that compete with our oral drug delivery system.

Many of these competitors have and employ greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop 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. Drugs resulting from our research and development efforts or from our joint efforts with collaborative partners therefore may not be commercially competitive 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, may depend substantially upon reimbursement of the costs of the resulting drugs and related treatments at acceptable levels from government authorities, private health insurers and other organizations, including health maintenance organizations, or HMOs. To date, the costs of our marketed products Aphthasol® and Zindaclin® generally have been reimbursed at acceptable levels; however, the amount of such reimbursement in the United States or elsewhere may be decreased in the future or may be unavailable for any drugs that we may develop in the future. Limited reimbursement for the cost of any drugs that we develop may reduce the demand for, or the price of such drugs, which would hamper our ability to obtain collaborative partners to commercialize our drugs, or to obtain a sufficient financial return on our own manufacture and commercialization of any future drugs.

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

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

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In 1996, the 5% amlexanox paste product was approved for sale in the United States. To date, the product sales have not been significant. On July 22, 2002, we acquired the rights to it from Block Drug Company. The product has been approved in the UK and Canada but has not been launched in any markets other than the United States. We re-launched Aphthasol® in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004 as well as the quarter ended March 31, 2005.

We received regulatory approval from the FDA to manufacture and sell OraDisc™ A in September 2004 and are proceeding with our manufacturing and marketing plans for 2005.

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 healthcare 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. 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. As a result, although we, together with our subsidiaries, are either the owner or licensee to 24 U.S. patents and to 19 U.S. patent applications now pending, and 8 European patents and 15 European patent applications, we cannot assure investors that any additional patents will issue from any of the patent applications owned by, or licensed to, us. Furthermore, any rights that we may have under issued patents may not provide us with significant protection against competitive products or otherwise be commercially viable.

Our patents for the following technologies expire in the years and during the date ranges indicated below:

- 5% amlexanox paste in 2011
- Zindaclin® and Residerm® between 2007 and 2011
- OraDisc™ in 2020
- AP5280 in 2021
- AP5346 in 2021
- Mucoadhesive technology, patents are pending
- Vitamin mediated technology between 2006 and 2019

In addition, patents may have been granted to third parties or may be granted covering products or processes that are necessary or useful to the development of our drug candidates. If our drug candidates or processes are found to infringe upon the patents or otherwise impermissibly utilize the intellectual property of others, our development, manufacture and sale of such drug candidates could be severely restricted or prohibited. In such event, we may be required to obtain licenses from third parties to utilize the patents or proprietary rights of others. We cannot assure

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investors 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.

Due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified management, 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 only limited investments in manufacturing, production, sales or regulatory compliance resources. 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, 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 investors, which could limit the ability of our other stockholders to influence the direction of the company.

Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.) and Heartland Advisors, Inc. beneficially owned approximately 11.9% and 10.9%, respectively, of our common stock as of March 31, 2005. Accordingly, they collectively may have the ability to significantly influence or determine the election of all of our directors or the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of our other stockholders.

Provisions of our charter documents could discourage an acquisition of our company that would benefit our stockholders and may have the effect of entrenching, and making it difficult to remove, management.

Provisions of our Certificate of Incorporation, By-laws and Stockholders Rights Plan may make it more difficult for a third party to acquire control of the company, even if a change 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. Further, the existence of these corporate governance provisions could have the effect of entrenching management and making it more difficult to change our management.

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 or shares that we may issue or be obligated to issue in the future. Substantially, all of the 15,724,734 shares of our common stock that are outstanding as of May 9, 2005, are unrestricted and freely tradable or tradable pursuant to a resale registration statement or under Rule 144 of the Securities Act.

Failure to achieve and maintain effective internal controls could have a material adverse effect on our business.

Effective internal controls are necessary for us to provide reliable financial reports. If we cannot provide reliable financial reports, our operating results could be harmed. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

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While we continue to evaluate and improve our internal controls, we cannot be certain that these measures will ensure that we implement and maintain adequate controls over our financial processes and reporting in the future. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm our operating results or cause us to fail to meet our reporting obligations.

For the year ended December 31, 2004, our management determined that our internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our auditors identified two material weaknesses in our internal controls and procedures during the course of their evaluation for the year ended December 31, 2004 in the areas of segregation of duties and as a result of an aggregation of three separate significant deficiencies where the effectiveness of the controls are dependent on segregation of duties. Their conclusion did not result in any adjustments to the annual or interim consolidated financial statements or affect their report dated March 31, 2005 reflecting their opinion on the financial statements. Management and our Audit Committee have determined to engage an outside accounting/finance consulting firm to perform procedures quarterly that are designed to assist in the maintaining and monitoring of an effective control environment and to mitigate the risk related to a lack of segregation of duties between senior accounting/finance personnel. The consulting firm is expected to report and take instructions directly from our Audit Committee, although management will be involved in assisting in determining the scope of the quarterly and annual procedures. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in our reported financial information, which could have a material adverse effect on our stock price.

RISKS RELATED TO THIS OFFERING

Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings

Sales of our common stock in the public market following this offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all. Of the 15,724,734 shares of common stock outstanding as of May 9, 2005, 15,724,734 shares are, or will be, freely tradable without restriction, unless held by our "affiliates." Some of these shares may be resold under Rule 144.

The sale of shares pursuant to the Securities Purchase Agreement will have a dilutive impact on our stockholders. The fixed price under the Secured Convertible Debentures is \$4.00. Therefore, if the full amount of the convertible debentures or \$2,6330,000 is converted into shares of our common stock, up 658,250 shares of common stock will be issued to the holders of the Secured Convertible Debentures at any time up to the maturity date of the Secured Convertible Debentures on March 30, 2006. The holders of these shares may sell them in the market immediately, which could cause our stock price to decline. In addition, the interest on the Secured Convertible Debentures may be payable, at the option of the holders, in shares of our common stock as opposed to cash, which could have a further dilutive impact on our stockholders and could cause our stock price to decline.

Existing shareholders will experience significant dilution from our sale of shares under the Standby Equity Distribution Agreement

We are to a great extent dependent on external financing to fund our operations. Our financial needs may be partially provided from the Standby Equity Distribution Agreement. The issuance of shares of our common stock under the Standby Equity Distribution Agreement will have a dilutive impact on our other stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock.

As a result, our net income per share could decrease in future periods, and the market price of our common stock could decline. In addition, the lower our stock price, the more shares of common stock we will have to issue under

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the Standby Equity Distribution Agreement to draw down the full amount. If our stock price is lower, then our existing stockholders would experience greater dilution.

Under the Standby Equity Distribution Agreement, Cornell Capital Partners will pay less than the then-prevailing market price of our common stock

The common stock to be issued under the Standby Equity Distribution agreement will be issued at a 2% discount of the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. In addition, Cornell Capital Partners will retain 3.5% from each advance. Based on this discount, Cornell Capital Partners will have an incentive to sell immediately to realize the gain on the 2% discount. These discounted sales could cause the price of our common stock to decline, based on increased selling of our common stock.

The selling stockholders intend to sell their shares of common stock in the market, which sales may cause our stock price to decline

The selling stockholders intend to sell in the public market 7,649,823 shares of our common stock being registered in this offering. That means that up to 7,649,823 shares may be sold pursuant to this registration statement. Such sales may cause our stock price to decline. Our officers and directors and our shareholders who are significant shareholders, as defined by the SEC, will continue to be subject to the provisions of various insider trading and rule 144 regulations.

The sale of our stock under the Standby Equity Distribution Agreement could encourage short sales by third parties, which could contribute to the future decline of our stock price

In many circumstances, the provisions of a Standby Equity Distribution Agreement have the potential to cause a significant downward pressure on the price of a company's common stock. This is especially the case if the shares being placed into the market exceed the market's ability to take up the increased stock or if we have not performed in such a manner to show that the equity funds raised will be used for growth. Such an event could place further downward pressure on the price of our common stock. We may request numerous draw downs pursuant to the terms of the Standby Equity Distribution Agreement. Even if we use the Standby Equity Distribution Agreement to grow our revenues and profits or invest in assets that are materially beneficial to us, the opportunity exists for short sellers and others to contribute to the future decline of our stock price. If there are significant short sales of stock, the price decline that would result from this activity will cause the share price to decline more so which in turn may cause long holders of the stock to sell their shares thereby contributing to sales of stock in the market. If there is an imbalance on the sell side of the market for the stock the price will decline.

It is not possible to predict those circumstances whereby short sales could materialize or to what the share price could drop. In some companies that have been subjected to short sales the stock price has dropped to near zero. This could happen to our stock price.

The price you pay in this offering will fluctuate and may be higher or lower than the prices paid by other people participating in this offering

The price in this offering will fluctuate based on the prevailing market price of our common stock on AMEX. Accordingly, the price you pay in this offering may be higher or lower than the prices paid by other people participating in this offering.

We may not be able to access sufficient funds under the Standby Equity Distribution Agreement when needed

We are dependent on external financing to fund our operations. Our financing needs maybe partially provided from the Standby Equity Distribution Agreement. No assurances can be given that such financing will be available in sufficient amounts or at all when needed, in part, because the amount of each advance is subject to a maximum advance amount of \$1,000,000, and we may not submit any advance within five trading days of a prior advance.

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We may not be able to obtain a cash advance under the equity distribution agreement if Cornell Capital Partners holds more than 9.9% of our common stock.

In the event Cornell Capital Partners holds more than 9.9% of our then-outstanding common stock, we will be unable to obtain a cash advance under the Standby Equity Distribution Agreement. A possibility exists that Cornell Capital Partners may own more than 9.9% of our outstanding common stock at a time when we would otherwise plan to make an advance under the Standby Equity Distribution Agreement. In that event, if we are unable to obtain additional external funding or generate revenue from the sale of our products, we could be forced to curtail or cease our operations.

AMEX listing requirements.

Our common stock is presently listed on AMEX under the symbol "AKC". All companies listed on AMEX are required to comply with certain continued listing standards, including corporate governance requirements, maintaining stockholders' equity at required levels, obtaining shareholder approvals for certain transactions, share price requirements and other rules and regulations of AMEX. AMEX listing requirements allow us to issue a maximum aggregate of 3,089,422 shares of our common stock in connection with our Secured Convertible Debentures and the Standby Equity Distribution Agreement without receipt of shareholder approval. Any issuances above such amount would require shareholder approval or would be a violation of AMEX regulations. We are not in compliance with this stockholders' equity standard as of March 31, 2005. On April 28, 2005, we received notice from the staff of AMEX indicating that we were not in compliance with Section 1003(a)(i) of the AMEX Company Guide, in that our stockholders' equity is less than \$2 million and we have sustained losses from continuing operations and/or net losses in two of our three most recent fiscal years; with Section 1003(a)(ii) of the AMEX Company Guide, in that our stockholders' equity is less than \$4 million and we have sustained losses from continuing operations and/or net losses in three of our four most recent fiscal years; and with Section 1003(a)(iii) of the AMEX Company Guide, in that our stockholders' equity is less than \$6 million and we have sustained losses from continuing operations and/or net losses in our five most recent fiscal years. In order to maintain listing of our common stock on AMEX, we must submit a plan by May 31, 2005, advising AMEX of the actions we have taken, or will take, that would bring us into compliance with the applicable listing standards. We intend to submit a compliance plan to AMEX by May 31, 2005. If AMEX accepts the plan, we may be able to continue our listing during the plan period of up to 8 months, during which time we will be subject to periodic review to determine whether we are making progress consistent with the plan. If AMEX does not accept our plan, or even if accepted, if we are not in compliance with the continued listing standards at the end of the 8 month period or do not make progress consistent with the plan during such period, AMEX may initiate delisting proceedings with respect to our common stock. In the event that our common stock is delisted from AMEX its market value and liquidity could be materially adversely affected.

Cornell Capital Partners may sell shares of our common after we deliver an advance notice during the pricing period, which could cause our stock price to decline.

Cornell Capital Partners is deemed to beneficially own the shares of common stock corresponding to a particular advance on the date that we deliver an advance notice to Cornell Capital Partners, which is prior to the date the stock is delivered to Cornell Capital Partners. Cornell Capital Partners may sell such shares any time after we deliver an advance notice. Accordingly, Cornell Capital Partners may sell such shares during the pricing period. Such sales may cause our stock price to decline.

FORWARD-LOOKING STATEMENTS

This Prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, and that involve risks and uncertainties, including, but not limited to the uncertainties associated with research and development activities, clinical trials, our ability to raise capital, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations, future cash flow, the timing and receipt of licensing and milestone revenues, the future success of our marketed products and products in development, our ability to manufacture amlexanox products in commercial quantities, our sales projections, and the sales projections of our licensing partners, our ability to achieve licensing milestones and other risks described below as well as those discussed elsewhere in this Prospectus, documents

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incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission. We intend the forward-looking statements to be covered by the safe harbor for forward-looking statements in these sections. These forward-looking statements include, without limitation, statements relating to anticipated product approvals and timing thereof, the terms of future licensing arrangements, our ability to secure additional financing for our operations, our belief that our net cash burn rate for the next twelve months to be approximately \$600,000 per month, our ability to repay our outstanding debt obligations, our ability to fund our operations (other than debt repayment) through March 2006, and our expected capital expenditures. These forward-looking statements are usually accompanied by words such as “believe,” “anticipate,” “plan,” “seek,” “expect,” “intend” and similar expressions. The forward-looking information is based on various factors and was derived using numerous assumptions.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward-looking statements due to a number of factors, including those set forth below under “Risk Factors” and elsewhere in this Prospectus. The factors set forth above under “Risk Factors” and other cautionary statements made in this Prospectus should be read and understood as being applicable to all related forward-looking statements wherever they appear in this Prospectus. The forward-looking statements contained in this Prospectus represent our judgment as of the date of this Prospectus. We caution readers not to place undue reliance on such statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

SELLING STOCKHOLDERS

The following table presents information regarding the selling stockholders. The selling shareholders are the entities who have assisted in or provided financing to us. A description of each selling shareholder’s relationship to us and how each selling shareholder acquired the shares to be sold in this offering is detailed in the information immediately following this table.

Selling Stockholder	Shares Beneficially Owned Before Offering (1)	Percentage of Outstanding Shares Beneficially Owned Before Offering	Shares to be Acquired Under the Standby Equity Distribution Agreement	Percentage of Outstanding Shares to be Acquired Under the Standby Equity Distribution Agreement	Shares to be Sold in the Offering	Percentage of Outstanding Shares Beneficially Owned After Offering
Cornell Capital Partners, LP	550,625(2)	3.50%	6,741,573	42.87%	7,292,198(5)	0%
Highgate House Funds, Ltd.	354,125(3)	2.25%	—	—	354,125	0%
Newbridge Securities Corporation	3,500(4)	*	—	—	3,500	0%
Total:	908,250	5.78%	6,741,573	—	7,649,823	0%

*Less than 1%

- (1) Applicable percentage of ownership is based on 15,724,734 shares of common stock outstanding as of May 9, 2005, together with securities exercisable or convertible into shares of common stock within 60 days of May 9, 2005, for each stockholder. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the Commission under the Securities and Exchange Act of 1934, as amended. Shares of common stock issuable pursuant to options, warrants and convertible securities are treated as outstanding for computing the percentage of the person holding such securities but are not treated as outstanding for computing the percentage of any other person. Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to shares, subject to community property laws where applicable. Shares not outstanding but deemed beneficially owned by virtue of the right of a person or group to acquire them within 60 days are treated as outstanding only for purposes of determining the number of and percent owned by such person or group.
- (2) Includes 146,500 shares of common stock that were received as a commitment fee, 50,000 shares of common stock issuable if we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement, 329,125 shares of common stock underlying the Secured Convertible Debentures, and

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25,000 shares of common stock that were issued in connection with the issuance of the Secured Convertible Debentures; provided, however, the terms of the Secured Convertible Debentures provide that in no event shall Cornell Capital Partners be entitled to convert such debentures for a number of shares which, upon giving effect to the conversion, would cause the aggregate number of shares beneficially owned by Cornell Capital Partners and its affiliates to exceed 4.99% of our outstanding shares of common stock following such conversion.

- (3) Includes 329,125 shares of common stock underlying the Secured Convertible Debentures and 25,000 shares of common stock that were issued in connection with the issuance of the Secured Convertible Debentures; provided, however, the terms of the Secured Convertible Debentures provide that in no event shall Highgate House Funds be entitled to convert such debentures for a number of shares which, upon giving effect to the conversion, would cause the aggregate number of shares beneficially owned by Highgate House Funds, Ltd. and its affiliates to exceed 4.99% of our outstanding shares of common stock following such conversion.
- (4) Includes 3,500 shares of common stock that were issued as a placement agent fee.
- (5) Includes the 6,741,573 shares of common stock acquired by Cornell Capital Partners under the Standby Equity Distribution Agreement, 146,500 shares of common stock that were received as a commitment fee, 50,000 shares of common stock issuable if we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement, 329,125 shares of common stock underlying the Secured Convertible Debentures, and 25,000 shares of common stock that were issued in connection with the issuance of the Secured Convertible Debentures.

Shares Acquired In Financing Transactions

The following information contains a description of each selling shareholder's relationship to us and how each selling shareholder acquired the shares to be sold in this offering is detailed below. None of the selling stockholders have held a position or office, or had any other material relationship, with us, except as follows:

Cornell Capital Partners. Cornell Capital Partners is the investor under the Standby Equity Distribution Agreement and a holder of our Secured Convertible Debentures and shares of our common stock. All investment decisions of, and control of, Cornell Capital Partners are held by its general partner, Yorkville Advisors, LLC. Mark Angelo, the managing member of Yorkville Advisors, makes the investment decisions on behalf of and controls Yorkville Advisors. Cornell Capital Partners acquired all shares being registered in this offering in financing transactions with us. Those transactions are explained below:

- **Standby Equity Distribution Agreement.** On March 30, 2005, we entered into a Standby Equity Distribution Agreement with Cornell Capital Partners. Pursuant to the Standby Equity Distribution Agreement, we may, at our discretion, periodically sell to Cornell Capital Partners shares of common stock for a total purchase price of up to \$15.0 million. For each share of common stock purchased under the Standby Equity Distribution Agreement, Cornell Capital Partners will pay us 98% of, or a 2% discount to, the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. Further, Cornell Capital Partners will retain 3.5% of each advance under the Standby Equity Distribution Agreement. In connection with the Standby Equity Distribution Agreement, Cornell Capital Partners received a one-time commitment fee in the form of 146,500 shares of common stock. We will issue Cornell Capital Partners 50,000 shares of our common stock within ten business days of the date that we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement. We are registering 6,741,573 shares of common stock in this offering which may be issued under the Standby Equity Distribution Agreement.

There are certain risks related to sales by Cornell Capital Partners, including:

- o The outstanding shares will be issued based on discount to the market rate. As a result, the lower the stock price around the time Cornell Capital Partners is issued shares, the greater chance that Cornell Capital Partners gets more shares. This could result in substantial dilution to the interests of other holders of common stock.

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- o To the extent Cornell Capital Partners sells its shares of common stock, our common stock price may decrease due to the additional shares in the market. This could allow Cornell Capital Partners to sell a greater number of shares of our common stock, the sales of which would further depress the stock price.
- o The significant downward pressure on the price of our common stock as Cornell Capital Partners sells material amounts of common stocks could encourage short sales by third parties. This could place further downward pressure on the price of our common stock.
- **Convertible Debentures.** We issued the Secured Convertible Debentures to Cornell Capital Partners and Highgate House Funds, Ltd. in the original principal amount of \$2,633,000 pursuant to a Securities Purchase Agreement entered into on March 30, 2005. The debentures are convertible at Cornell Capital Partners option at the fixed conversion price of \$4.00. If the full amount of the convertible debentures or \$2,633,000 is converted into shares of our common stock, up to an aggregate of 658,259 shares of common stock will be issued to Cornell Capital Partner and Highgate House Funds, Ltd. at any time up to the maturity date of the Secured Convertible Debentures on March 30, 2006. However, this does not take into account the 4.99% ownership limitation under the Secured Convertible Debentures. Assuming the holders of the Secured Convertible Debentures had converted the \$2,633,000 in Secured Convertible Debentures into 685,250 shares of common stock at a fixed price of \$4.00 on December 31, 2004, this would represent an immediate dilution to any new stockholders of \$0.68 per share. The Secured Convertible Debentures are secured by all of our assets and in addition, we could be required to issue and the holders would have the ability to sell up to 2,891,723 shares of our common stock. The Secured Convertible Debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005, to the extent that the Secured Convertible Debentures have not been converted to common stock. We have the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, we also issued to the holders an aggregate of 50,000 shares of our common stock. We are registering 658,259 shares of common stock underlying the Secured Convertible Debentures and the 50,000 shares of common stock issued to the holders of the Secured Convertible Debentures in this offering.

Highgate House Funds, Ltd. Highgate House Funds, Ltd. is a holder of our Secured Convertible Debentures and shares of our common stock. All investment decisions of, and control of, Highgate House Funds, Ltd. are held by its general partner, Yorkville Advisors, LLC. Mark Angelo, the managing member of Yorkville Advisors, makes the investment decisions on behalf of and controls Yorkville Advisors. Highgate House Funds, Ltd. acquired all shares being registered in this offering in financing transactions with us, as explained in above.

Newbridge Securities Corporation. We engaged Newbridge Securities Corporation, an unaffiliated registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. Newbridge Securities Corporation was paid a fee of 3,500 shares of our common stock on March 30, 2005, under a Placement Agent Agreement. These shares are being registered in this offering. All investment decisions of Newbridge Securities Corporation are made by its President, Guy Amico.

USE OF PROCEEDS

This Prospectus relates to shares of our common stock that may be offered and sold from time to time by certain selling stockholders. There will be no proceeds to us from the sale of shares of common stock in this offering. However, we will receive the proceeds from the sale of shares of common stock to Cornell Capital Partners under the Standby Equity Distribution Agreement. The purchase price of the shares purchased under the Standby Equity Distribution Agreement will be equal to 98% of the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. We will pay Cornell Capital 3.5% of each advance as an additional fee.

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Pursuant to the Standby Equity Distribution Agreement, the amount of each advance is subject to a maximum advance amount of \$1,000,000, and we may not submit any advance within five trading days of a prior advance, or request more than \$15.0 million over twenty-four months from the effective date of this Prospectus. We may not request advances if the shares to be issued in connection with such advances would result in Cornell Capital Partners owning more than 9.99% of our outstanding common stock.

For illustrative purposes only, we have set forth below our intended use of proceeds for the range of net proceeds indicated below to be received under the Standby Equity Distribution Agreement. The table assumes estimated offering expenses of \$49,053, plus the 3.5% retainage payable to Cornell Capital Partners under the Standby Equity Distribution Agreement. The figures below are estimates only, and may be changed due to various factors, including the timing of the receipt of the proceeds.

Gross Proceeds	\$5,000,000	\$10,000,000	\$15,000,000
Net Proceeds	4,776,000	9,601,010	14,426,000
Number of shares issued under the Standby Equity Distribution Agreement at an assumed offering price of \$2.225	2,247,191	4,494,382	6,741,573
<u>Use of Proceeds:</u>			
General Working Capital	4,776,000	9,601,000	14,426,000

TOTAL:

The Standby Equity Distribution Agreement limits our use of proceeds to general corporate purposes, including, without limitation, the payment of loans incurred by us. However, we cannot use the net proceeds from this offering for the payment (or loan to any such person for the payment) of any judgment, or other liability, incurred by any executive officer, officer, director or employee of ours, except for any liability owed to such person for services rendered, or if any judgment or other liability is incurred by such person originating from services rendered to us, or we have indemnified such person from liability.

DILUTION

Our net tangible book value as of December 31, 2004 was a deficit of \$11,099,000 or -\$0.71 per share of common stock. Net tangible book value per share is determined by dividing our tangible book value (total tangible assets less total liabilities) by the number of outstanding shares of our common stock. Since this offering is being made solely by the selling stockholders and none of the proceeds will be paid to us, our net tangible book value will be unaffected by this offering. Our net tangible book value and our net tangible book value per share, however, will be impacted by the shares of our common stock to be issued under the Standby Equity Distribution Agreement. The amount of dilution will depend on the offering price and number of shares to be issued under the Standby Equity Distribution Agreement. The following example shows the dilution to new investors at an offering price of \$2.225 per share, which is in the range of the recent share price.

If we assume that we had issued 6,741,573 shares of common stock under the Standby Equity Distribution Agreement at an assumed offering price of \$2.225 per share (*i.e.*, the number of shares registered in this offering under the Equity Distribution Agreement), less retention fees of \$525,000 and offering expenses of \$49,053; our net tangible book value as of December 31, 2004 would have been \$3,327,000 or \$0.15 per share. Note that at an offering price of \$2.225; per share, we would receive net proceeds of \$14,426,000 of the \$15,000,000 available under the Equity Distribution Agreement. At an assumed offering price of \$2.225, Cornell Capital Partners would receive a discount of \$525,000 on the purchase of 6,741,573 shares of common stock. Such an offering would represent an immediate increase in net tangible book value to existing stockholders of \$0.86 per share and an immediate dilution to new stockholders of \$2.07 per share.

The following table illustrates the per share dilution:

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Assumed public offering price per share		\$ 2.25
Net tangible book value per share before this offering	\$(11,099,000)	
Increase attributable to new investors	\$ 14,426,000	
Net tangible book value per share after this offering		\$3,327,000
Dilution per share to new stockholders		\$ 2.07

The offering price of our common stock is based on the then-existing market price. In order to give prospective investors an idea of the dilution per share they may experience, we have prepared the following table showing the dilution per share at various assumed offering prices:

ASSUMED OFFERING PRICE	NO. OF SHARES TO BE ISSUED (1)	DILUTION PER SHARE TO NEW INVESTORS
\$2.225	6,741,573	\$2.07
\$1.67	6,741,573	\$1.52
\$1.11	6,741,573	\$0.96
\$0.56	6,741,573	\$0.41

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- (1) This represents the maximum number of shares of common stock that are being registered under the Standby Equity Distribution Agreement at this time.

STANDBY EQUITY DISTRIBUTION AGREEMENT

Summary

On March 30, 2005, we entered into a Standby Equity Distribution Agreement with Cornell Capital Partners. Pursuant to the Standby Equity Distribution Agreement, we may, at our discretion, periodically sell to Cornell Capital Partners shares of common stock for a total purchase price of up to \$15.0 million. For each share of common stock purchased under the Standby Equity Distribution Agreement, Cornell Capital Partners will pay 98% of, or a 2% discount to, the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. The number of shares purchased by Cornell Capital Partners for each advance is determined by dividing the amount of each advance by the purchase price for the shares of common stock. Further, Cornell Capital Partners will retain 3.5% of each advance under the Standby Equity Distribution Agreement. Cornell Capital Partners is a private limited partnership whose business operations are conducted through its general partner, Yorkville Advisors, LLC. The effectiveness of the sale of the shares under the Standby Equity Distribution Agreement is conditioned upon us registering the shares of common stock with the Securities and Exchange Commission and obtaining all necessary permits or qualifying for exemptions under applicable state law. The costs associated with this registration will be borne by us. There are no other significant closing conditions to draws under the equity line.

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Standby Equity Distribution Agreement Explained

Pursuant to the Standby Equity Distribution Agreement, we may periodically sell shares of common stock to Cornell Capital Partners to raise capital to fund our working capital needs. The periodic sale of shares is known as an advance. We may request an advance every five trading days. A closing will be held six trading days after such written notice at which time we will deliver shares of common stock and Cornell Capital Partners will pay the advance amount. We may request cash advances under the Standby Equity Distribution Agreement once the underlying shares are registered with the SEC. Thereafter, we may continue to request cash advances until Cornell Capital Partners has advanced us a total amount of \$15,00,000 or 24 months after the effective date of this registration statement, whichever occurs first.

The amount of each advance is subject to a maximum amount of \$1,000,000, and we may not submit an advance within five trading days of a prior advance. The amount available under the Standby Equity Distribution Agreement is not dependent on the price or volume of our common stock. Our ability to request advances is conditioned upon us registering the shares of common stock with the SEC. In addition, we may not request advances if the shares to be issued in connection with such advances would result in Cornell Capital Partners owning more than 9.99% of our outstanding common stock. A possibility exists that Cornell Capital Partners may own more than 9.99% of our outstanding common stock at a time when we would otherwise plan to make an advance under the Standby Equity Distribution Agreement.

We do not have any agreements with Cornell Capital Partners regarding the distribution of such stock, although Cornell Capital Partners has indicated that it intends to promptly sell any stock received under the Standby Equity Distribution Agreement.

We cannot predict the actual number of shares of common stock that will be issued pursuant to the Standby Equity Distribution Agreement, in part, because the purchase price of the shares will fluctuate based on prevailing market conditions and we have not determined the total amount of advances we intend to draw. Nonetheless, we can estimate the number of shares of our common stock that will be issued using certain assumptions. Assuming we issued the number of shares of common stock being registered in the accompanying registration statement at a recent price of \$2.225 per share, we would issue 6,741,573 shares of common stock to Cornell Capital Partners for gross proceeds of \$15,000,000. These shares would represent 42.87% of our outstanding common stock upon issuance.

There is an inverse relationship between our stock price and the number of shares to be issued under the Standby Equity Distribution Agreement. That is, as our stock price declines, we would be required to issue a greater number of shares under the Standby Equity Distribution Agreement for a given advance. This inverse relationship is demonstrated by the following tables, which show the net cash to be received by us and the number of shares to be issued under the Standby Equity Distribution Agreement at a recent price of \$2.27 per share and 25%, 50% and 75% discounts to the recent price.

Net Cash To Access:

Market Price:	\$ 2.27	\$ 1.70	\$ 1.14	\$ 0.57
Purchase Price:	\$ 2.225	\$ 1.67	\$ 1.11	\$ 0.56
No. of Shares(1):	6,741,573	6,741,573	6,741,573	6,741,573
Total Outstanding (2):	21,781,057	21,781,057	21,781,057	21,781,057
Percent Outstanding (3):	30.95%	30.95%	30.95%	30.95%
Net Cash to Access:(4)	14,426,000	14,426,000	14,426,000	14,426,000

- (1) Represents the number of shares of common stock registered in the accompanying registration statement, which could be issued to Cornell Capital Partners under the Standby Equity Distribution Agreement at the prices set forth in the table.
- (2) Represents the total number of shares of common stock outstanding after the issuance of the shares to Cornell Capital Partners under the Standby Equity Distribution Agreement, not including shares issued under the convertible debentures.

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- (3) Represents the shares of common stock to be issued as a percentage of the total number shares outstanding.
- (4) Net cash equals the gross proceeds minus the 3.5% retainage and \$49,053 in offering expenses.

Proceeds used under the Standby Equity Distribution Agreement will be used in the manner set forth in the “Use of Proceeds” section of this Prospectus. We cannot predict the total amount of proceeds to be raised in this transaction because we have not determined the total amount of the advances we intend to draw. Cornell Capital Partners has the ability to permanently terminate its obligation to purchase shares of common stock from us under the Standby Equity Distribution Agreement if there shall occur any stop order or suspension of the effectiveness of this registration statement for an aggregate of seventy-five (75) trading days other than due to acts by Cornell Capital Partners or if we fail materially to comply with certain terms of the Standby Equity Distribution Agreement, which failure remains uncured for thirty (30) days after notice from Cornell Capital Partners.

All fees and expenses under the Standby Equity Distribution Agreement will be borne by us. We expect to incur expenses of approximately \$49,053 in connection with this registration, consisting primarily of professional fees. In connection with the Standby Equity Distribution Agreement, Cornell Capital Partners received a one-time commitment fee in the form of 146,500 shares of our common stock. We will issue Cornell Capital Partners 50,000 shares of our common stock within ten business days of the date that we issue and sell to Cornell Capital Partners in excess of \$10.0 million shares of our common stock under the Standby Equity Distribution Agreement.

PLAN OF DISTRIBUTION

The selling stockholders have advised us that the sale or distribution of our common stock owned by the selling stockholders may be effected directly to purchasers by the selling stockholders as principals or through one or more underwriters, brokers, dealers or agents from time to time in one or more transactions (which may involve crosses or block transactions) (i) on AMEX or in any other market on which the price of our shares of common stock are quoted or (ii) in transactions otherwise than on AMEX or in any other market on which the price of our shares of common stock are quoted. Any of such transactions may be effected at market prices prevailing 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 prices, in each case as determined by the selling stockholders or by agreement between the selling stockholders and underwriters, brokers, dealers or agents, or purchasers. If the selling stockholders effect such transactions by selling their shares of common stock to or through underwriters, brokers, dealers or agents, such underwriters, brokers, dealers or agents may receive compensation in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of common stock for whom they may act as agent (which discounts, concessions or commissions as to particular underwriters, brokers, dealers or agents may be in excess of those customary in the types of transactions involved).

Cornell Capital Partners is an “underwriter” within the meaning of the Securities Act of 1933 in connection with the sale of common stock under the Standby Equity Distribution Agreement. Cornell Capital Partners will pay us 98% of, or a 2% discount to, the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. In addition, Cornell Capital Partners will retain 3.5% of the proceeds received by us under the Standby Equity Distribution Agreement, and received a one-time commitment fee in the form of 146,500 shares of our common stock. We will issue Cornell Capital Partners 50,000 shares of our common stock within ten business days of the date that we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement. The 2% discount, the 3.5% retainage and commitment fee in the form of 196,500 shares of common stock are underwriting discounts. In addition, we engaged Newbridge Securities Corporation, an unaffiliated registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. Newbridge Securities Corporation was paid a fee of 3,500 shares of our common stock on March 30, 2005, under a Placement Agent Agreement.

Cornell Capital Partners was formed in February 2000 as a Delaware limited partnership. Cornell Capital Partners is a domestic hedge fund in the business of investing in and financing public companies. Cornell Capital Partners does not intend to make a market in our stock or to otherwise engage in stabilizing or other transactions intended to help support the stock price. Prospective investors should take these factors into consideration before purchasing our common stock.

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Under the securities laws of certain states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. The selling stockholders are advised to ensure that any underwriters, brokers, dealers or agents effecting transactions on behalf of the selling stockholders are registered to sell securities in all fifty states. In addition, in certain states the shares of common stock 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 the expenses incident to the registration, offering and sale of the shares of common stock to the public hereunder other than commissions, fees and discounts of underwriters, brokers, dealers and agents. If any of these other expenses exists, we expect the selling stockholders to pay these expenses. We have agreed to indemnify Cornell Capital Partners and its controlling persons against certain liabilities. We estimate that the expenses of the offering to be borne by us will be approximately \$49,053, as well as the retention of 3.5% of the gross proceeds received under the Standby Equity Distribution Agreement. In addition, we engaged Newbridge Securities Corporation, a registered broker-dealer, to act as placement agent in connection with the Standby Equity Distribution Agreement. Newbridge Securities Corporation was paid a fee of 3,500 shares of our common stock for its services on March 30, 2005, under a Placement Agent Agreement. The offering expenses consist of: a SEC registration fee of \$2,052.88, printing expenses of \$5,000, accounting fees of \$20,000, legal fees of \$20,000, and miscellaneous expenses of \$2,000. We will not receive any proceeds from the sale of any of the shares of common stock by the selling stockholders. We will, however, receive proceeds from the sale of common stock under the Standby Equity Distribution Agreement.

The selling stockholders are subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and its regulations, including, Regulation M. Under Registration M, the selling stockholders or their agents may not bid for, purchase, or attempt to induce any person to bid for or purchase, shares of our common stock while such selling stockholders are distributing shares covered by this Prospectus. Pursuant to the requirements of Item 512 of Regulation S-B and as stated in Part II of this Registration Statement, we must file a post-effective amendment to the accompanying Registration Statement once informed of a material change from the information set forth with respect to the Plan of Distribution.

In the event Cornell Capital Partners holds more than 9.9% of our then-outstanding common stock, we will be unable to obtain a cash advance under the Equity Distribution Agreement. A possibility exists that Cornell Capital Partners may own more than 9.9% of our outstanding common stock at a time when we would otherwise plan to make an advance under the Equity Distribution Agreement. In that event, if we are unable to obtain additional external funding or generate revenue from the sale of our products, we could be forced to curtail or cease our operations.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and related notes included in this Prospectus.

Overview

We are an emerging pharmaceutical company focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities. We are a Delaware corporation.

Together with our subsidiaries, we have proprietary patents or rights to several drug delivery technology platforms, including:

- synthetic polymer targeted delivery,
- vitamin mediated targeted delivery,
- vitamin mediated oral delivery,
- bioerodible cross-linker technology,

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- mucoadhesive disc technology,
- hydrogel particle aggregate technology, and
- Residerm® topical delivery.

In addition, we are marketing in the United States — Aphthasol®, the first FDA approved product for the treatment of canker sores. We are developing new formulations and delivery forms of amlexanox including mucoadhesive disc delivery and mucoadhesive liquid delivery.

Our amlexanox 5% paste is marketed in the US as Aphthasol®. We selected Contract Pharmaceuticals Ltd. Canada as our manufacturer of amlexanox 5% paste and it completed full scale production in September 2004. We re-launched Aphthasol® in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004 as well as the quarter ended March 31, 2005.

Since our inception, we have devoted our resources primarily to fund our research and development programs. We have been unprofitable since inception and to date have received limited revenues from the sale of products. We cannot assure investors that we will be able to generate sufficient product revenues to attain profitability on a sustained basis or at all. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance. As of March 31, 2005, our accumulated deficit was \$66,887,000.

On February 24, 2004, we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of \$5.40. We received gross proceeds of \$9,663,000 from this sale and had legal and placement-related expenses of \$647,000. The investors also received 5 year warrants at an exercise price of \$7.10 per share to purchase 447,344 shares of our common stock and the placement agents received warrants in the offering at an exercise price of \$5.40 per share to purchase 156,481 shares of our common stock.

Recent Developments

On May 11, 2005, we announced that Kerry P. Gray resigned as our President and Chief Executive Officer, effective as of May 10, 2005. Mr. Gray resigned from our Board of Directors and from all other positions held with us, effective as of May 10, 2005. We entered into a Separation Agreement with Mr. Gray dated as of May 10, 2005. Pursuant to the terms of the Separation Agreement, Mr. Gray has agreed to provide us with certain post-termination assistance. He also agreed to maintain the confidentiality of our proprietary information and to a customary mutual release of claims with us. The Separation Agreement provides for an immediate cash payment to Mr. Gray of \$225,000 and payments of \$33,333.33 each month for a period of 18 months, which payments are secured by a lien on our assets. We are required to issue 3,500 shares of our common stock to Mr. Gray each month for a period of 18 months following May 10, 2005. The Separation Agreement also provides that all of Mr. Gray's outstanding stock options and shares of restricted stock immediately and fully vested and options remain exercisable for a period of two years.

On May 11, 2005, we announced that Rosemary Mazanet, M.D., Ph.D, has been named by the Board of Directors as our Acting Chief Executive Officer, effective as of May 11, 2005. The agreement is memorialized in a Letter Agreement with us, dated May 10, 2005. Dr. Mazanet's title will be Acting Chief Executive Officer and she will report directly to, and be subject to the direction of, our Board of Directors. Dr. Mazanet will be paid a weekly salary of \$7,500 for the duration of the Letter Agreement, and she was granted a non-qualified stock option of 30,000 shares of our common stock, with an exercise price equal to the last sale price on May 10, 2005. Dr. Mazanet's option will vest monthly over a six month period. The Letter Agreement also grants Dr. Mazanet similar employee benefits as our other executive officers, D&O insurance coverage and a signing bonus of \$30,000. The Letter Agreement provides for additional option or cash grants based on milestones to be agreed upon by Dr. Mazanet and our Board of Directors.

On April 18, 2005, we announced that we executed an exclusive License Agreement granting Discus Dental, Inc. the US marketing rights for amlexanox. The rights granted are for amlexanox 5% paste, currently marketed in the United States for the treatment of canker sores and OraDisc™ A, which was approved by the FDA in September 2004 for the same indication. In addition, we granted Discus Dental the rights to any future product improvements for amlexanox in oral disease. Under the terms of the agreement, Discus Dental will pay us a licensing fee and will make milestone payments.

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On March 30, 2005, we finalized an agreement with Cornell Capital Partners and Highgate House Funds providing funding in the form of the Secured Convertible Debentures for net proceeds of approximately \$2,360,000, and the Standby Equity Distribution Agreement under which, subject to terms of the Agreement, we can draw up to \$15,000,000 in working capital over a 2-year period.

Results of Operations

Comparison of Years Ended December 31, 2004 and 2003

Our licensing revenue in 2004 was \$104,000, as compared to licensing revenue of \$729,000 in 2003, a decrease of \$625,000 due to one time initial licensing fees in 2003. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2004 and 2003 was from several agreements including agreements related to various amlexanox projects and Residerm®.

Product sales of Aphthasol® totaled \$351,000 in 2004, as compared to product sales of \$532,000 in 2003. Sales were limited in 2004 due to a supply interruption of the product. Supplies were manufactured in the third quarter of 2004 and sales commenced in late September 2004.

Royalty income for 2004 was \$94,000 as compared to \$34,000 in 2003, an increase of \$60,000 due to higher sales of Zindaclin® in additional countries.

Our total research spending for the year ended December 31, 2004 was \$5,417,000, as compared to \$6,096,000 in 2003, a decrease of \$679,000. The decrease in expenses was the result of:

- lower clinical development costs (\$622,000) for our OraDisc™ A clinical trial, which was completed in 2003;
- lower costs for the AP5280 and AP5346 polymer platinate clinical trials (\$374,000) of which the AP5280 trial was completed in 2003; and
- other net decreases (\$201,000).

These decreases were partially offset by:

- higher production and testing costs for Aphthasol® and start-up costs for OraDisc™ A (\$117,000);
- higher scientific salary and salary related expenses due to additional staff (\$269,000); and
- higher expenses in our Australian operations (\$132,000).

Our cost of product sales was \$239,000 for 2004 as compared to \$277,000 in 2003, a decrease of \$38,000. The decrease in the cost of product sales was due to reduced Aphthasol® sales in 2004 due to the supply interruption.

Our total general and administrative expenses were \$3,199,000 for 2004, an increase of \$685,000 over 2003 expenses of \$2,514,000, due to:

- higher professional fees and expenses (\$339,000) principally due to increased accounting and legal fees associated with compliance with the Sarbanes-Oxley Act, new contracts and legal proceedings;
- higher business consulting expenses for new business development activities (\$88,000);
- higher fees for a healthcare consultant review (\$133,000);
- higher patent and license expenses (\$51,000);
- higher salary and related expense (\$63,000); and
- other net increases (\$11,000).

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Depreciation and amortization was \$773,000 in 2004 as compared to \$621,000 in 2003, an increase of \$152,000 due to the impairment of a license that is no longer effective (\$109,000) and from the acquisition of new capital equipment (\$43,000).

Our loss from operations in 2004 was \$9,079,000 as compared to a loss of \$8,213,000 in 2003.

Interest and miscellaneous income was \$226,000 for 2004 as compared to \$2,559,000 for 2003, a decrease of \$2,333,000. The decrease in miscellaneous income of \$2,280,000 was due to a one time payment associated with a settlement agreement with Block Drug Company in 2003 and a decrease in interest income due to lower cash balances and lower interest rates in 2004 as compared with 2003.

Interest and miscellaneous expense was \$1,385,000 for 2004 as compared to \$1,281,000 for the same period in 2003, an increase of \$104,000. The expense to record an impairment in investment was \$112,000 and the change in interest expense was \$8,000.

Net loss for 2004 was \$10,238,000, or a \$0.68 basic and diluted loss per common share compared with a loss of \$6,935,000, or a \$0.52 basic and diluted loss per common share, for 2003.

Comparison of Years Ended December 31, 2003 and 2002

Our licensing revenue in 2003 was \$729,000, as compared to licensing revenue of \$853,000 in 2002, a decrease of \$124,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2003 and 2002 was from several agreements, including agreements related to various amlexanox projects and Residerm®.

Product sales of Aphthasol® totaled \$532,000 in 2003, as compared to product sales of \$194,000 in 2002. Our first sales were recorded in December 2002. As a result of the Aphthasol® supply situation discussed above, there were no product sales of Aphthasol® between July 2003 and August 2004.

In 2002, we had a research and development agreement that provided \$89,000 in revenue. The agreement expired in 2002 and we had no such revenue in 2003.

Royalty income for 2003 was \$34,000 as compared to \$11,000 in 2002, an increase of \$23,000.

Our total research spending for the year ended December 31, 2003 was \$6,096,000, as compared to \$7,024,000 in 2002, a decrease of \$928,000. The decrease in expenses was the result of:

- lower clinical development costs (\$812,000) for the amlexanox OraDisc™ project; and
- lower development and clinical development costs for our polymer platinate project (\$773,000).

These decreases were offset by:

- higher salary and salary related expenses due to additional staff (\$278,000);
- higher expenses due to the full year impact of our Australian operations (\$254,000);
- higher internal lab costs due to the additional staff and projects (\$102,000); and
- other net increases (\$23,000).

Our cost of product sales was \$277,000 for 2003 as compared to \$107,000 in 2002. The commencement of our Aphthasol® sales began in the fourth quarter of 2002.

Our total general and administrative expenses were \$2,514,000 for 2003, an increase of \$237,000 over 2002 expenses of \$2,277,000, due to:

- higher professional fees and expenses (\$81,000);
- higher shareholder-investor relations expenses (\$144,000);

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- higher patent and license expenses (\$60,000);
- higher salary and related expense (\$50,000); and
- higher rent expenses (\$31,000).

These increases were offset by lower withholding taxes on foreign revenues (\$129,000).

Depreciation and amortization was \$621,000 in 2003 as compared to \$439,000 in 2002, an increase of \$182,000 primarily resulting from the acquisition of new capital equipment and a full year of amortization of acquired patents.

Our loss from operations in 2003 was \$8,213,000 as compared to a loss of \$8,700,000 in 2002.

Our interest and miscellaneous income was \$2,559,000 for 2003 as compared to \$594,000 for 2002, an increase of \$1,965,000. The increase in miscellaneous income of \$2,280,000 was due to a one time settlement agreement with Block Drug Company relating to Block's contractual obligation to supply Aphthasol® to us. Pursuant to the settlement, Block made a onetime cash payment to us and we were also relieved of certain future payment obligations to Block under the Asset Sale Agreement pursuant to which we purchased from Block the assets relating to amlexanox. Under the settlement agreement, Block was relieved of its obligation to supply amlexanox to us. The increase in interest and miscellaneous income was partially offset by a decrease in interest income due to lower cash balances and lower interest rates in 2003 as compared with 2002.

Interest expense was \$1,281,000 for 2003 as compared to \$1,278,000 for the same period in 2002, an increase of \$3,000.

Net loss for 2003 was \$6,935,000, or a \$0.52 basic and diluted loss per common share compared with a loss of \$9,384,000, or a \$0.72 basic and diluted loss per common share, for 2002.

Comparison of First Quarter Ended March 31, 2005 versus First Quarter Ended March 31, 2004

Our licensing revenue in the first quarter of 2005 was \$11,000, as compared to licensing revenue of \$4,000 in same quarter of 2004, an increase of \$7,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2005 and 2004 was from several agreements, including agreements related to various amlexanox projects and Residerm®.

There were \$117,000 in product sales of Aphthasol® in the first quarter of 2005, as compared to no sales in the first quarter of 2004 due to a supply interruption in such period. Aphthasol® product sales recommenced in September 2004.

Royalty income in the first quarter of 2005 was \$27,000, as compared to \$16,000 in the first quarter of 2004. Increased sales of Zindaclin® resulted in \$11,000 higher royalty income.

Total research spending for the first quarter of 2005 was \$1,319,000, as compared to \$1,144,000 for the same period in 2004, an increase of \$175,000. The increase in expenses was primarily the result of:

- higher costs (\$82,000) for pre-production of OraDisc™ A;
- higher costs for product and clinical trials for AP5346 (\$71,000); and
- higher salary and related costs due to additional employees (\$74,000).

The increase in expenses was partially offset by lower costs for other projects (\$52,000).

Our cost of product sales was \$102,000 in the first quarter of 2005, as compared to \$26,000 in the first quarter of 2004, an increase of \$76,000. The increase in cost of product sales was due to increased product sales and fees associated with sales in 2005 versus no sales and fees in 2004 .

Total general and administrative expenses were \$689,000 for the first quarter of 2005, a decrease of \$65,000 as compared to the same period in 2004. The decrease in spending was due primarily to the following:

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- lower patent expenses (\$119,000), due to new patent expenses and PCT filings in 2004;
- lower salary and related costs (\$16,000);
- lower investor relations expenses (\$10,000);

The decrease in general and administrative expenses is partially offset by:

- higher license fees (\$39,000);
- higher professional fees (\$15,000);
- higher general business consulting fees (\$15,000); and
- by other net increases (\$11,000).

Depreciation and amortization was \$164,000 for the first quarter of 2005 as compared to \$160,000 for the same period in 2004 reflecting an increase of \$4,000. The increase in depreciation and amortization was due to increased depreciation resulting from the acquisition of additional capital assets.

Total operating expenses in the first quarter of 2005 were \$2,274,000 as compared to total operating expenses of \$2,084,000 for the same period in 2004, an increase of \$190,000.

Loss from operations in the first quarter of 2005 was \$2,119,000 as compared to a loss of \$2,064,000 for the same period in 2004, an increase of \$55,000.

Interest and miscellaneous income was \$10,000 for the first quarter of 2005 as compared to \$33,000 for the same period in 2004, a decrease of \$23,000. The decrease in interest income was due to lower cash balances and lower interest rates in 2005 as compared with 2004.

Interest expense was \$313,000 for the first quarter of 2005 as compared to \$320,000 for the same period in 2004, a decrease of \$7,000.

Net loss in the first quarter of 2005 was \$2,422,000, or a \$0.16 basic and diluted loss per common share, compared with a loss of \$2,351,000, or a \$0.17 basic and diluted loss per common share for the same period in 2004, an increased loss of \$71,000 in 2005.

Liquidity and Capital Resources

We have funded our operations primarily through private sales of common stock and convertible notes and our principal source of liquidity is cash and cash equivalents. Contract research payments, licensing fees and milestone payments from corporate alliances and mergers have also provided funding for operations. As of March 31, 2005, our cash and cash equivalents and short-term investments were \$2,888,000 and our working capital deficit was \$(9,474,000). Our working capital deficit at March 31, 2005 of \$(9,474,000), as compared to our working capital deficit as of December 31, 2004 of \$(7,788,000), which represented a decrease of our working capital of \$1,686,000. The decrease in working capital was due mainly to the loss from operations for the three months ended March 31, 2005.

As of March 31, 2005, we had a working capital deficit of approximately \$(9,474,000). As of that date, we did not have enough capital to achieve our near, medium or long-term goals. On March 30, 2005, we entered into the Standby Equity Distribution Agreement with Cornell Capital Partners, which management believes will provide sufficient capital to achieve our short-term goals, and depending upon our financial results, may provide sufficient capital to meet our long-term goals.

Under the Standby Equity Distribution Agreement, we may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to \$15,000,000. The purchase price for the shares is equal to their market price, which is defined in the Standby Equity Distribution Agreement as 98% of the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the Equity Line of Credit. The amount of each draw down

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is subject to a maximum amount of \$1,000,000. The terms of the Standby Equity Distribution Agreement do not allow us to make draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our outstanding shares of common stock. Cornell Capital Partners received a one-time commitment fee of 146,500 shares of our common stock. We will issue Cornell Capital Partners 50,000 shares of our common stock within ten business days of the date that we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement. On March 30, 2005, we entered into a Placement Agent Agreement in escrow with Newbridge Securities Corporation, a registered broker-dealer, pursuant to which we paid a one-time placement agent fee of 3,500 shares of common stock.

In addition, as of March 30, 2005, we executed a Securities Purchase Agreement with Cornell Capital Partners and Highgate House Funds. Under the Securities Purchase Agreement, Cornell Capital Partners and Highgate House Funds purchased an aggregate of \$2,633,000 principal amount of Secured Convertible Debentures from us (net proceeds to us of \$2,360,000). The Secured Convertible Debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the Secured Convertible Debenture has not been converted to common stock. Each Secured Convertible Debenture is convertible into shares of our common stock at the holder's option any time up to maturity at a conversion price equal to \$4.00. If the full amount of the Secured Convertible Debentures or \$2,633,000 is converted into shares of our common stock, up to 685,250 shares of common stock will be issued to the holders of the Secured Convertible Debentures at any time up to the maturity date of the Secured Convertible Debentures on March 30, 2006. However, this does not take into account the 4.99% ownership limitation under the Secured Convertible Debentures. Assuming the holders of the Secured Convertible Debentures had converted the \$2,633,000 in Secured Convertible Debentures into 685,250 shares of common stock at a fixed price of \$4.00 on December 31, 2004, this would represent an immediate dilution to any new stockholders of \$0.68 per share. The Secured Convertible Debentures are secured by all of our assets and in addition, we could be required to issue and the holders would have the ability to sell up to 2,891,723 shares of our common stock. We have the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, we issued an aggregate of 50,000 shares of our common stock to the holders of the Secured Convertible Debentures.

On February 24, 2004, we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of \$5.40. We received gross proceeds of \$9,663,000 from this sale and had legal and placement-related expenses of \$647,000. The investors also received 5 year warrants at an exercise price of \$7.10 per share to purchase 447,344 shares of our common stock and the placement agents received warrants in the offering at an exercise price of \$5.40 per share to purchase 156,481 shares of our common stock.

We have also issued an aggregate of \$13,530,000 of convertible notes, which are due in two parts - \$8,030,000 is due on September 13, 2005 and \$5,500,000 is due on September 13, 2008. The notes, which bear interest at a rate of 7.7% per annum with \$1,042,000 of interest due annually on each September 13, may convert to common stock at a conversion price of \$5.50 per share. Should the holders of the notes not elect to convert them to common stock, or if we are not able to force the conversion of the notes by their terms, we must repay the amounts on the due dates. A failure to restructure our existing convertible notes or obtain necessary additional capital in the future could jeopardize our operations. We do not have sufficient funds to repay our convertible notes at their maturity. We may not be able to restructure the convertible notes or obtain additional financing to repay them on terms acceptable to us, if at all. If we raise additional funds by selling equity securities, the relative equity ownership of our existing investors would be diluted and the new investors could obtain terms more favorable than previous investors. A failure to restructure our convertible notes or obtain additional funding to repay the convertible notes and support our working capital and operating requirements, could cause us to be in default of our convertible notes and prevent us from making expenditures that are needed to allow us to maintain our operations.

We have generally incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of March 31, 2005 of \$66,891,000. We expect that our existing capital resources together with anticipated licensing revenues and royalties will be adequate to fund our current level of operations through March 2006 excluding any obligation to repay the convertible notes, the debt service on the convertible notes and the secured convertible notes. We cannot assure investors that we will ever be able to generate significant product revenue or achieve or sustain profitability. We currently do not have the cash resources to repay our Convertible Notes due in September 2005 or our Secured

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Convertible Notes in March 2006. Our financing plan through the use of the Standby Equity Distribution Agreement or other sales of equity are expected to provide the resources to repay such notes.

We plan to expend substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products, including research and development with respect to our acquired and developed technology. Our future capital requirements and adequacy of available funds will depend on many factors, including:

- the ability to convert, repay or restructure our outstanding convertible notes and secured convertible notes;
- the successful commercialization of amlexanox and Zindaclin®;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- successful regulatory filings.

We have devoted substantially all of our efforts and resources to research and development conducted on our own behalf. The following table summarizes research and development spending by project category (in thousands), which spending includes, but is not limited to, payroll and personnel expense, lab supplies, preclinical expense, development cost, clinical trial expense, outside manufacturing expense and consulting expense:

<u>Project</u>	<u>Twelve Months ended December 31,</u>		<u>Three Months ended March 30,</u>	<u>Inception To Date (1)</u>
	<u>2004</u>	<u>2003</u>	<u>2005</u>	
Polymer Platinite (AP5280 and AP5346)	\$ 2,330	\$ 2,559	\$ 600	\$ 15,711
OraDisc™	1,084	1,387	2154	7,521
Bioerodible Hydrogel Technology and Nanoparticles and Nanoparticle Networks	951	978	215	3,514
Vitamin Mediated Targeted Delivery	748	614	55	1,758
Mucoadhesive Liquid Technology (MLT)	51	34		1,480
Others (2)	253	524	235	5,255
Total	\$ 5,417	\$ 6,096	\$ 1,319	\$ 33,239

(1) Cumulative spending from inception through December 31, 2004.

(2) The following projects are among the ones included in this line item: Carbohydrate targeting, amlexanox cream and gel and other related projects.

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Due to uncertainties and certain of the risk factors described above, including those relating to our ability to successfully commercialize our drug candidates, our ability to obtain necessary additional capital to fund operations in the future, our ability to successfully manufacture our products and our product candidates in clinical quantities or for commercial purposes, government regulation to which we are subject, the uncertainty associated with preclinical and clinical testing, intense competition that we face, market acceptance of our products and protection of our intellectual property, it is not possible to reliably predict future spending or time to completion by project or product category or the period in which material net cash inflows from significant projects are expected to commence. If we are unable to timely complete a particular project, our research and development efforts could be delayed or reduced, our business could suffer depending on the significance of the project and we might need to raise additional capital to fund operations, as discussed in the risk factors above, including without limitation those relating to the uncertainty of the success of our research and development activities and our ability to obtain necessary additional capital to fund operations in the future. As discussed in such risk factors, delays in our research and development efforts and any inability to raise additional funds could cause us to eliminate one or more of our research and development programs.

We plan to continue our policy of investing available funds in certificates of deposit, money market funds, government securities and investment-grade interest-bearing securities. We do not invest in derivative financial instruments.

Critical Accounting Policies and Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United State of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reported period. In applying our accounting principles, we must often make individual estimates and assumptions regarding expected outcomes or uncertainties. As you might expect, the actual results or outcomes are often different than the estimated or assumed amounts. These differences are usually minor and are included in our consolidated financial statements as soon as they are known. Our estimates, judgments and assumptions are continually evaluated based on available information and experience. Because of the use of estimates inherent in the financial reporting process, actual results could differ from those estimates.

Revenue

Revenue associated with up-front license, technology access and research and development funding payments under collaborative agreements is recognized ratably over the performance period of the agreement. Determination of the performance period involves judgment on management's part.

Asset Impairment

On January 1, 2002, we adopted SFAS 142, "*Goodwill and Other Intangible Assets*." Upon adoption, we performed a transitional impairment test on our recorded intangible assets that consisted primarily of acquisition related goodwill and license intangibles. We also performed an annual impairment test in the fourth quarter of 2004. The analysis resulted in no goodwill impairment charge in 2004. We will be required to perform this test on at least an annual basis.

Our intangible assets at December 31, 2004 consist primarily of goodwill, patents acquired in acquisitions and licenses, which were recorded at fair value on the acquisition date.

Based on an assessment of our accounting policies and underlying judgments and uncertainties affecting the application of those policies, we believe that our consolidated financial statements provide a meaningful and fair perspective of us. We do not suggest that other general factors, such as those discussed elsewhere in this report, could not adversely impact our consolidated financial position, results of operations or cash flows. The impairment test involves judgment on the part of management as to the value of goodwill, licenses and intangibles.

Off-Balance Sheet Transactions

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None

Contractual Obligations

Our contractual obligations including interest as of December 31, 2004 are set forth below.

	<u>Payment Due by Period</u>		
	Total	Less Than 1 Year	1-3 Years
Long-Term Debt			
Obligations	\$13,992,000	\$8,335,000	\$5,657,000
Interest	2,326,000	1,053,000	1,273,000
Capital Lease Obligations	118,000	82,000	36,000
Interest	8,000	7,000	1,000
Total	<u>\$16,444,000</u>	<u>\$9,477,000</u>	<u>\$6,967,000</u>

DESCRIPTION OF BUSINESS

Business

We are an emerging pharmaceutical company focused on developing both novel low development risk product candidates and technologies with longer-term major product opportunities.

Together with our subsidiaries, we have proprietary patents or rights to seven drug delivery technology platforms:

- synthetic polymer targeted delivery,
- vitamin mediated targeted delivery
- vitamin mediated oral delivery,
- bioerodible cross-linker technology,
- mucoadhesive disc technology,
- hydrogel particle aggregate technology, and
- Residerm® topical delivery.

In addition, we have acquired the amlexanox patents and technology for the treatment of mucosal and skin disorders.

We use our proprietary technology to develop products and product candidates. Our patents and trade secrets protect our marketed products, amlexanox 5% paste (marketed under the trade names Aphthasol® and Aptheal®) and Zindaclin®, and our product candidates that are currently in the drug development phase, DACH platinum (AP 5346), polymer platinate (AP 5280) and OraDisc™.

We are marketing amlexanox 5% paste, the first U.S. Food and Drug Administration (FDA) approved product for the treatment of canker sores, under the trade name Aphthasol® in the United States. In September 2001, ProStrakan Limited, our United Kingdom partner, received marketing authorization to market amlexanox 5% paste in the U. K. under the trade name Aptheal®. We have received marketing approval in 10 European Union countries following completion of the Mutual Recognition Procedure (MRP). Approval to market was granted in Austria, Germany, Greece, Finland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, and Sweden. We are developing new formulations and delivery forms of amlexanox, including mucoadhesive disc delivery. In 2004, we received approval of our new drug application for OraDisc™ A from the United States Food and Drug Administration (FDA). OraDisc™ A is an improved delivery system for amlexanox. The OraDisc™ technology is a proprietary mucoadhesive patch that gradually erodes and releases an active ingredient when applied to the inside of the mouth.

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In addition, ProStrakan has used our patented Residerm® technology to develop a zinc clindamycin formulation for the treatment of acne. ProStrakan began marketing zinc clindamycin in the United Kingdom under the trade name Zindaclin® in March 2002. The process to achieve marketing authorization for Zindaclin® throughout Europe has now been completed, with approvals in most European Union countries including the new member states and several non-European countries. We anticipate that in the next twelve months approvals will be obtained in additional other countries.

Key Developments

On May 11, 2005, we announced that Kerry P. Gray resigned as our President and Chief Executive Officer, effective as of May 10, 2005. Mr. Gray resigned from our Board of Directors and from all other positions held with us, effective as of May 10, 2005. We entered into a Separation Agreement with Mr. Gray dated as of May 10, 2005. Pursuant to the terms of the Separation Agreement, Mr. Gray has agreed to provide us with certain post-termination assistance. He also agreed to maintain the confidentiality of our proprietary information and to a customary mutual release of claims with us. The Separation Agreement provides for an immediate cash payment to Mr. Gray of \$225,000 and payments of \$33,333.33 each month for a period of 18 months, which payments are secured by a lien on our assets. We are required to issue 3,500 shares of our common stock to Mr. Gray each month for a period of 18 months following May 10, 2005. The Separation Agreement also provides that all of Mr. Gray's outstanding stock options and shares of restricted stock immediately and fully vested and options remain exercisable for a period of two years.

On May 11, 2005, we announced that Rosemary Mazanet, M.D., Ph.D, has been named by the Board of Directors as our Acting Chief Executive Officer, effective as of May 11, 2005. The agreement is memorialized in a Letter Agreement with us, dated May 10, 2005. Dr. Mazanet's title will be Acting Chief Executive Officer and she will report directly to, and be subject to the direction of, our Board of Directors. Dr. Mazanet will be paid a weekly salary of \$7,500 for the duration of the Letter Agreement, and she was granted a non-qualified stock option of 30,000 shares of our common stock, with an exercise price equal to the last sale price on May 10, 2005. Dr. Mazanet's option will vest monthly over a six month period. The Letter Agreement also grants Dr. Mazanet similar employee benefits as our other executive officers, D&O insurance coverage and a signing bonus of \$30,000. The Letter Agreement provides for additional option or cash grants based on milestones to be agreed upon by Dr. Mazanet and our Board of Directors.

On April 18, 2005, we announced that we executed an exclusive License Agreement granting Discus Dental, Inc. the US marketing rights for amlexanox. The rights granted are for amlexanox 5% paste, currently marketed in the United States for the treatment of canker sores and OraDisc™ A, which was approved by the FDA in September 2004 for the same indication. In addition, we granted Discus Dental the rights to any future product improvements for amlexanox in oral disease. Under the terms of the agreement, Discus Dental will pay us a licensing fee and will make milestone payments.

As of March 30, 2005, we executed the Standby Equity Distribution Agreement with Cornell Capital Partners. Under the Standby Equity Distribution Agreement, we may issue and sell to Cornell Capital Partners shares of our common stock for a total purchase price of up to \$15,000,000. The purchase price for the shares is equal to their market price, which is defined in the Standby Equity Distribution Agreement as 98% of the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the Equity Line of Credit. The amount of each draw down is subject to a maximum amount of \$1,000,000. The terms of the Standby Equity Distribution Agreement do not allow us to make draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our outstanding shares of common stock. Because of the ability of Cornell Capital to sell shares under a registration statement and Cornell Capital Partner's business model, we do not believe that Cornell would accumulate 9.9% of our outstanding common stock. In connection with the Standby Equity Distribution Agreement, Cornell Capital Partners received a one-time commitment fee of 146,500 shares of our common stock. We will issue Cornell Capital Partners 50,000 shares of our common stock within ten business days of the date that we issue and sell to Cornell Capital Partners in excess of \$10.0 million of our common stock under the Standby Equity Distribution Agreement. On March 30, 2005, we entered into a Placement Agent Agreement with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the Placement Agent Agreement, we paid a one-time placement agent fee of 3,500 shares of common stock.

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In addition, as of March 30, 2005, we executed a Securities Purchase Agreement with Cornell Capital Partners and Highgate House Funds. Under the Securities Purchase Agreement, Cornell Capital Partners and Highgate House Funds purchased an aggregate of \$2,633,000 principal amount of our Secured Convertible Debentures (net proceeds to us of \$2,360,000). The Secured Convertible Debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the Secured Convertible Debenture has not been converted to common stock. Each Secured Convertible Debenture is convertible into shares of our common stock at the holder's option any time up to maturity at a conversion price equal to \$4.00. If the full amount of the Secured Convertible Debentures or \$2,633,000 is converted into shares of our common stock, up to 685,250 shares of common stock will be issued to the holders of the Secured Convertible Debentures at any time up to the maturity date of the Secured Convertible Debentures on March 30, 2006. However, this does not take into account the 4.99% ownership limitation under the Secured Convertible Debentures. Assuming the holders of the Secured Convertible Debentures had converted the \$2,633,000 in Secured Convertible Debentures into 685,250 shares of common stock at a fixed price of \$4.00 on December 31, 2004, this would represent an immediate dilution to any new stockholders of \$0.68 per share. The Secured Convertible Debentures are secured by all of our assets and in addition, we could be required to issue and the holders would have the ability to sell up to 2,891,723 shares of our common stock. We have the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, we issued to the holders an aggregate of 50,000 shares of our common stock.

OraDisc™ A was approved by the FDA in September 2004.

This successful development is an important technology milestone that supports the development of the OraDisc™ range of products. To achieve OraDisc™ A approval, in addition to performing the necessary clinical studies to prove efficacy, we conducted an irritation study, a 28-day safety study and drug distribution studies. Additionally, we demonstrated safety in patients down to 12 years of age. Patients in the 700 patient clinical study and 28-day safety study completed a survey that produced very positive results with regard to perceived effectiveness, ease of application, ability of the disc to remain in place and purchase intent. These data give strong support to our overall development program. The survey data confirms market research studies that indicate a strong patient acceptance of this delivery device.

On February 24, 2004, we closed a private placement sale of our common stock pursuant to which we sold 1,789,371 shares of our common stock at a per share price of \$5.40. We received gross proceeds of \$9,663,000 from this offering and had legal and placement-related expenses of \$647,000. The investors also received 5 year warrants to purchase 447,344 shares of our common stock at an exercise price of \$7.10 per share and the placement agents received warrants in the offering to purchase 156,481 shares of our common stock at an exercise price of \$5.40 per share.

On January 8, 2004, we announced that we had signed a licensing agreement with Wyeth Consumer Healthcare, a division of Wyeth, granting Wyeth the North American rights to develop and market an over-the-counter (OTC) product utilizing our OraDisc™ technology pending any required regulatory approvals. This agreement grants an exclusive license to market the OraDisc™ product in the United States, Canada and Mexico, with additional rights to extend the marketing rights worldwide.

We were incorporated in Wyoming in 1974 as Chemex Corporation, and in 1983 we changed our name to Chemex Pharmaceuticals, Inc. We changed our state of incorporation from Wyoming to Delaware on June 30, 1989. In 1996 we merged with Access Pharmaceuticals, Inc., a private Texas corporation, and changed our name to Access Pharmaceuticals, Inc. Our principal executive office is located at 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207; our telephone number is (214) 905-5100.

Products

We have used our drug delivery technology platforms to develop the following products and product candidates:

Marketed Products

Aphthasol® and Aptheal® (Amlexanox 5% Paste)

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Amlexanox 5% paste is the first drug approved by the FDA for the treatment of canker sores. Independent market research indicates that more than 8 million patients visit dentists per year in the United States with complaints of canker sores. Current estimates indicate that approximately 20% of the U.S. adult population suffers from canker sores.

We completed a Phase IV study in Ireland in November 2000 to determine if the application of amlexanox 5% paste at the first sign or symptom of canker sores can abort ulcer formation or further accelerate healing. The results confirmed that amlexanox 5% paste was effective in preventing the formation of an ulcer when used at the first sign or symptom of the disease. If this label extension is approved by regulatory authorities, it could provide a major marketing opportunity to expand use of the product and to attract sufferers of canker sores to contact medical practitioners to request the product.

On July 22, 2002, we acquired from GlaxoSmithKline the patents, trademarks and technology covering the use of amlexanox for the treatment of mucosal and skin disorders. The two major components of the acquisition are the US marketing rights to amlexanox 5% paste, which is currently marketed for the treatment of canker sores under the trademark Aphthasol®, and the remaining worldwide marketing rights for this indication which were the subject of a prior licensing agreement between the companies.

On April 18, 2005, we announced that we executed an exclusive License Agreement granting Discus Dental, Inc. the US marketing rights for amlexanox. The rights granted are for amlexanox 5% paste, currently marketed in the United States for the treatment of canker sores and OraDisc™ A, which was approved by the FDA in September 2004 for the same indication. In addition, we granted Discus Dental the rights to any future product improvements for amlexanox in oral disease. Under the terms of the agreement, Discus Dental will pay us a licensing fee and will make milestone payments.

We licensed the exclusive United Kingdom and Ireland rights for the sale and marketing of amlexanox 5% paste for the treatment of canker sores to ProStrakan in August 1998. Under the terms of this license, ProStrakan was responsible for and assumed all costs associated with the regulatory approval process, including product registration, for amlexanox in the United Kingdom and the European Union (EU). Additionally, ProStrakan will make milestone payments to us on achievement of performance objectives and we will receive royalties on product sales of amlexanox.

An international outlicensing program for amlexanox is ongoing. In addition to our license agreements with Discus Dental and ProStrakan, licensing agreements have been executed with Zambon Group for France, Germany, Holland, Belgium, Luxembourg, Switzerland, Brazil, Columbia and Italy; Meda AB for Scandinavia, the Baltic states and Iceland; Laboratorios Esteve for Spain, Portugal and Greece; Mipharm S.p.A. for Italy; Paladin Labs Inc. for Canada, EpiTan, Ltd. for Australia and New Zealand, and Orient Europharma, Co., Ltd for Taiwan, Hong-Kong, Philippines, Thailand and Singapore. Contract Pharmaceuticals Ltd. Canada has also been selected as our European supplier of amlexanox 5% paste and has been approved for European supply.

ProStrakan received marketing authorization for amlexanox 5% paste in the United Kingdom in September 2001. ProStrakan's trade name for the product is Aptheal®. Approval to market was granted in Austria, Germany, Greece, Finland, Ireland, Luxembourg, The Netherlands, Norway, Portugal, and Sweden. Approvals were not received under the Mutual Recognition Procedure for France, Italy and Belgium. We plan to reapply for approvals in such countries.

The Therapeutic Products Programme, the Canadian equivalent of the FDA, has issued a notice of compliance permitting the sale of amlexanox 5% paste, called Aphera®, in Canada to Paladin Labs Inc., our Canadian partner.

Residerm® A gel – Zindaclin® (Zinc-Clindamycin)

The complexing of zinc to a drug has the effect of enhancing the penetration of the drug into the skin and the retention of the drug in the skin. This phenomenon is called the "reservoir effect," and it makes zinc potentially effective for the delivery of dermatological drugs. We have a broad patent covering the use of zinc for such purposes. This technology is called ResiDerm®.

We have developed, in conjunction with ProStrakan, zinc clindamycin for the treatment of acne which is marketed under the trade name Zindaclin®. Topical acne drugs constitute an approximately \$750 million per year market and

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clindamycin is a widely prescribed drug for the treatment of acne. Clinical studies indicate that the addition of zinc results in Zindaclin® being as effective applied once daily as the market leading clindamycin product applied twice daily. The activity of zinc and clindamycin, the improved stability of the product and the potential for zinc to overcome certain bacterial resistance are other potential product benefits.

In February 1998, we licensed the exclusive worldwide rights for the manufacturing, sales and marketing of zinc clindamycin pursuant to a license agreement with ProStrakan. Under the terms of the license agreement, ProStrakan has agreed to fund the development costs of zinc clindamycin and any additional compounds developed utilizing our zinc patent, including product registrations. We will share equally in all milestone payments received from the sublicensing of the compound. In addition, we will receive a royalty on sales of products based on this technology.

ProStrakan currently is marketing zinc clindamycin in the United Kingdom under the trade name Zindaclin®. The process to achieve marketing authorization for Zindaclin® throughout Europe now has been completed, with approvals in most European Union countries including the new member states and several non-European countries. We anticipate that in the next twelve months approvals will be obtained in additional countries. In addition, in May 2002 ProStrakan signed a Licensing Agreement with Fujisawa GmbH, which granted a license to Fujisawa for rights to market Zindaclin® in continental western Europe. Additional licenses and or distribution agreements have been signed in other countries with other companies.

Milestone Payments And Royalties By Product

The following table reflects aggregate milestone payments received through March 31, 2005, aggregate possible milestone payments under agreements signed as of March 31, 2005, and royalties received through March 31, 2005.

Product	Milestones	Aggregate Possible Milestones	Royalties
	Received through 3/31/05		Received through 3/31/05
Aphthasol® and OraDisc™	\$ 1,446,000	\$ 6,172,000	\$ —
Zindaclin®	\$ 1,426,000	\$ 1,168,000	\$ 165,000
OraDisc™ B	\$ 400,000	\$ 2,800,000	\$ —

Products in Development Status

Polymer Platinate

Chemotherapy, surgery and radiation are the major components in the clinical management of cancer patients. Chemotherapy is usually the primary treatment of hematologic malignancies, which cannot be excised by surgery. Chemotherapy is increasingly used as an adjunct to radiation and surgery to improve their effectiveness and serves as the primary therapy for some solid tumors and metastases. For chemotherapeutic agents to be effective in treating cancer patients, however, the agent must reach the target cells in effective quantities with minimal toxicity in normal tissues.

The current optimal strategy for chemotherapy involves exposing patients to the most intensive cytotoxic regimens that they can tolerate and clinicians attempt to design a combination of chemotherapeutic drugs, a dosing schedule and a method of administration to increase the probability that cancerous cells will be destroyed while minimizing the harm to healthy cells. Notwithstanding clinicians' efforts, most current chemotherapeutic drugs have significant shortcomings that limit the efficacy of chemotherapy. For example, certain cancers are inherently unresponsive to chemotherapeutic agents. Alternatively, other cancers may initially respond, but subgroups of cancer cells acquire resistance to the drug during the course of therapy and the resistant cells may survive and cause a relapse. Serious toxicity, including bone marrow suppression, renal toxicity, neuropathy, or irreversible cardiotoxicity, are some of the limitations of current anti-cancer drugs that can prevent their administration in curative doses.

Currently, platinum compounds are one of the largest selling categories of chemotherapeutic agents, with annual sales in excess of \$2.0 billion. As is the case with all chemotherapeutic drugs, the use of such compounds is associated with serious systemic side effects. The drug delivery goal therefore is to enhance delivery of the drug to the tumor and minimize the amount of drug affecting normal organs in the body.

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Polymer Platininate (AP 5346) DACH Platinum

The extensive experience we have gained developing AP5280 has been applied to extend our platinum developments to include the DACH form of platinum.

Oxaliplatin, another form of DACH platinum, which was initially approved in France and in Europe in 1999 for the treatment of colorectal cancer is now also being marketed in the United States and is generating worldwide sales in excess of \$1.5 billion annually. Carboplatin and Cisplatin, two approved platinum chemotherapy drugs, are not indicated for the treatment of metastatic colorectal cancer. Oxaliplatin, in combination with 5-fluorouracil and folinic acid is indicated for the first-line treatment of metastatic colorectal cancer in Europe and the U.S. The colorectal cancer market is a significant opportunity as there are over 500,000 reported new cases annually in the developed world, increasing at a rate of approximately three percent per year.

Utilizing the biocompatible water-soluble polymer HPMA as a drug carrier, AP5346 links DACH platinum to the polymer in a manner which permits the selective release of platinum in tumors. The polymer capitalizes on the biological differences in the permeability of blood vessels at tumor sites versus normal tissue. In this way, tumor selective delivery and platinum release is achieved. The ability to inhibit tumor growth has been evaluated in more than ten preclinical models. Compared with the marketed product Oxaliplatin, AP5346 showed superiority in a number of these models. Preclinical studies of the delivery of platinum to tumors in an animal model have shown that, compared with oxaliplatin at equitoxic doses, AP5346 delivers in excess of 16 times more platinum to the tumor. An analysis of tumor DNA, which is the main target for anti-cancer platinum agents, has shown that AP5346 delivers approximately 14 times more platinum to tumor DNA. Results from preclinical efficacy studies conducted in the B16 and other tumor models have also shown that AP5346 is superior to oxaliplatin in inhibiting the growth of tumors. An extensive preclinical package has been developed supporting the development of AP5346.

In the first quarter of 2005, we completed a Phase I clinical study in a multi-center study conducted in Europe, enrolled approximately 26 patients. The reporting of this study is expected to be completed in the second quarter of 2005. The European trial was designed to identify the maximum tolerated dose, dose limiting toxicities, the pharmacokinetics of the platinum in plasma and the possible antitumor activity of AP5346. The open-label, non-randomized, dose-escalation Phase I study was performed at two European centers. AP5346 was administered as an intravenous infusion over one hour, once a week on days 1, 8 and 15 of each 28-day cycle to patients with solid progressive tumors. We have obtained preliminary reports on results in 26 patients with a broad cross-section of tumor types, with doses ranging from 80-1,280 mg Pt/m².

Of the 26 patients, 10 were not evaluable for tumor response, principally due to withdrawal from the study prior to completing the required cycle. Of the 16 evaluable patients, 2 demonstrated a partial response and 4 experienced stable disease. One of the patients who attained a partial response had a melanoma with lung metastasis; a CT scan revealed a tumor decrease of greater than 50%. The other patient who responded had ovarian cancer; she had a reduction in lymph node metastasis and remission of a liver metastasis. Also of note, a patient with cisplatin resistant cervical cancer showed a short lasting significant reduction in lung metastasis after 3 doses. However, due to toxicity, the patient could not be retreated to determine whether the partial response could be maintained.

We received clearance in January 2005 from the US Food and Drug Administration for our Investigational New Drug Application (IND) for AP5346 allowing us to proceed with a Phase I clinical trial for this drug candidate. We plan to initiate a study of AP5346 in combination with fluorouracil and leucovorin to evaluate drug safety and to establish a starting dose for future Phase II studies utilizing this combination. Upon the successful completion of this Phase I study, we plan to initiate a Phase II study to determine the efficacy of AP5346 in combination with fluorouracil and leucovorin in colorectal cancer patients compared with the oxaliplatin/fluorouracil/leucovorin combination, which is used extensively to treat colorectal cancer.

Due to the superior pre-clinical and clinical results achieved relative to AP5280, AP5346 is now our lead clinical candidate. Additionally, since oxaliplatin has now been shown to have activity in solid tumors, in addition to colorectal cancer, we believe that the opportunity for AP5346 has been further expanded. Consequently, further development of AP5280 has been deferred pending the clinical results achieved with AP5346.

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OraDisc™

Treatment of oral conditions generally relies upon the use of medications formulated as gels and pastes, that are applied to lesions in the mouth. The duration of effectiveness of these medications is typically short because the applied dose is worn away through the mechanical actions of speaking, eating, and tongue movement, and is washed away by saliva flow. To address these problems, we developed a novel, cost-effective, commercially-viable, mucoadhesive film product that is bioerodible. This technology, known as OraDisc™, comprises a multi-layered film having an adhesive layer, a pre-formed film layer, and a coated backing layer. Depending upon the intended application, a pharmaceutically active compound can be formulated within any of these layers, providing for a wide range of potential applications. The disc is simply applied by pressing it against the inner surface of the mouth. The disc stays in place, eroding over a period of time, so that subsequent removal is unnecessary. The disc delivers the drug over a period of time controlled by the rate of erosion of the disc, which is in turn controlled by the formulation of the backing layer.

OraDisc™ A was initially developed as a drug delivery system to treat canker sores with the same active ingredient (amlexanox) that is used in Aphthasol®. We anticipate that higher amlexanox concentrations will be achieved at the disease site, increasing the effectiveness of the product, called OraDisc™ A.

OraDisc™ A was approved by the FDA in September 2004.

This successful development is an important technology milestone which supports the development of the OraDisc™ range of products. To achieve OraDisc™ A approval, in addition to performing the necessary clinical studies to prove efficacy, we conducted an irritation study, a 28-day safety study and drug distribution studies. Additionally, we demonstrated safety in patients down to 12 years of age. Patients in the 700 patient clinical study and 28-day safety study completed a survey which produced very positive results with regard to perceived effectiveness, ease of application, ability of the disc to remain in place and purchase intent. These data give strong support to our overall development program. The survey data confirms market research studies which indicate a strong patient acceptance of this delivery device.

Now that OraDisc™ A is approved as a prescription product, we intend to move this product to market as rapidly as possible through our partnership with Discus Dental, Inc.

It is also our objective to gain regulatory approval for OraDisc™ A in all the major global markets. In Western Europe the OraDisc™ A product has been licensed and we are in the process of extending our licensing coverage to cover all major global markets.

We have continued to develop the OraDisc™ technology, and we have generated or are exploring additional prototype drug delivery products, including those for pain palliation in the oral cavity, gingivitis, cough and cold treatment, breath freshener, tooth whitening and other dental applications. In January 2004, we announced the signing of an agreement with Wyeth Consumer Healthcare for the development of an OTC product based upon the OraDisc™ technology.

Mucoadhesive Liquid Technology (MLT)

Mucositis is a debilitating condition involving extensive inflammation of mouth tissue that affects an estimated 550,000 cancer patients in the United States undergoing chemotherapy and radiation treatment. Any treatment that would accelerate healing and/or diminish the rate of appearance would have a significant beneficial impact on the quality of life of these patients and may allow for more aggressive chemotherapy.

We filed an IND with the FDA in December 1999 and developed a Phase II protocol to investigate a mouthwash formulation for the prevention and treatment of mucositis in head and neck cancer patients treated with radiation with or without chemotherapy. Over 90% of head and neck cancer patients treated with radiation and chemotherapy experience mucositis. This study commenced in the first quarter of 2000. We enrolled 58 patients in the initial study which was performed at multiple sites throughout the United States.

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In July 2001, we announced results from our Phase II randomized clinical study of the prevention and treatment of mucositis. The data developed confirmed that our mucoadhesive liquid technology (MLT) could represent an important advancement in the management and prevention of mucositis.

The data were retrospectively compared with two historical patient databases to evaluate the potential advantages that this technology may represent in the prevention, treatment and management of mucositis. The patient evaluation was conducted using the oral mucositis assessment scale, which qualifies the disease severity on a scale of 0-5. Key highlights of the comparison with the historical patient databases are as follows:

- the average severity of the disease was reduced by approximately 40%;
- the maximum intensity of the mucositis was approximately 35% lower; and
- the median peak intensity was approximately 50% lower.

Given the results achieved with our MLT, and the fact that in the study an amlexanox rinse showed no additional benefit, we do not plan to conduct additional clinical studies evaluating amlexanox as a preventative product candidate for mucositis. Following the completion of the Phase II study we conducted additional formulation development work to optimize the MLT technology prior to advancing clinical development. The topical application of the MLT was tested for its ability to attenuate the course of radiation-induced oral mucositis in an established hamster model. The study results clearly indicate the ability to prevent the onset of ulcerative mucositis, or delay the onset and reduce the severity of mucositis. Further clinical development of this program has been placed on hold to focus our resources on our high potential cancer therapeutics. Further development will be dependent on securing a strategic partner.

Drug Development Strategy

A part of our integrated drug development strategy is to form creative alliances with centers of excellence in order to obtain alternative lead compounds while minimizing the overall cost of research. We have signed agreements with ProStrakan for the delivery of topical therapeutic agents which exploit our zinc patent. Additionally, certain of our polymer platinate technology have resulted in part from a research collaboration with The School of Pharmacy, University of London.

Our strategy is to initially focus on utilizing our technology in combination with approved drug substances to develop novel patentable formulations of existing therapeutic and diagnostic products. We believe that this will expedite product development, both preclinical and clinical, and ultimately product approval. To reduce financial risk and equity financing requirements, we are directing our resources to the preclinical and early clinical phases of development. Where the size of the necessary clinical studies and cost associated with the later clinical development phases are significant, we plan to outlicense to, or co-develop with, marketing partners our current product candidates.

We will continue to expand our internal core capabilities of chemistry, formulation, analytical methods development, clinical development, biology and project management to maximize product opportunities in a timely manner. We will, however, contract the manufacturing scaleup, certain preclinical testing and product production to research organizations, contract manufacturers and strategic partners. There will be some instances where there may be significant cost savings for us to do some manufacturing scaleup (such as with our OraDisc™ program) and preclinical testing. We will evaluate those instances and may do the work ourselves in order to achieve cost savings. Given the current cost containment and managed care environment both in the United States and overseas and the difficulty for a small company to effectively market its products, we do not currently plan to become a fully integrated pharmaceutical company.

Consequently, we expect to form strategic alliances for product development and to outlicense the commercial rights to development partners. By forming strategic alliances with major pharmaceutical and diagnostic companies, we believe that our technology can be more rapidly developed and successfully introduced into the marketplace.

Scientific Background

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The ultimate criteria for effective drug delivery is to control and optimize the localized release of the drug at the target site and rapidly clear the non-targeted fraction. Conventional drug delivery systems such as controlled release, sustained release, transdermal systems and others are designed for delivering active product into the systemic circulation over time with the objective of improving patient compliance. These systems do not address the biologically relevant issues such as site targeting, localized release and clearance of drug. The major factors that impact the achievement of this ultimate drug delivery goal are the physical characteristics of the drug and the biological characteristics of the disease target sites. The physical characteristics of the drug affect solubility in biological systems, its biodistribution throughout the body, and its interactions with the intended pharmacological target sites and undesired areas of toxicity. The biological characteristics of the diseased area impact the ability of the drug to selectively interact with the intended target site to allow the drug to express the desired pharmacological activity.

We believe that our drug delivery technology platforms are differentiated from conventional drug delivery systems in that they seek to apply a disease-specific approach to improve the drug delivery process with formulations to significantly enhance the therapeutic efficacy and reduce toxicity of a broad spectrum of products.

Core Drug Delivery Technology Platforms

Our current drug delivery technology platforms for use in cancer chemotherapy, dermatology and oral disease are:

- Synthetic Polymer Targeted Drug Delivery Technology;
- Vitamin Mediated Targeted Delivery Technology;
- Vitamin Mediated Oral Delivery Technology;
- Bioerodible Cross-Linker Technology;
- Mucoadhesive Disc Technology;
- Hydrogel Particle Aggregate Technology; and
- Residerm® Topical Delivery Technology.

Each of these platforms is discussed below:

Synthetic Polymer Targeted Drug Delivery Technology

In collaboration with The School of Pharmacy, University of London, we have developed a synthetic polymer technology, which utilizes hydroxypropylmethacrylamide with platinum, designed to exploit enhanced permeability and retention, or EPR, at tumor sites to selectively accumulate drug and control drug release. Many solid tumors possess vasculature that is hyperpermeable, or leaky, to macromolecules. In addition to this enhanced permeability, tumors usually lack effective lymphatic and/or capillary drainage. Consequently, tumors selectively accumulate circulating macromolecules, including, for example, up to 10% of an intravenous dose in mice. This effect has been termed EPR, and is thought to constitute the mechanism of action of styrene-maleic/anhydride-neocarzinostatin, or SMANCS, which is in regular clinical use in Japan for the treatment of hepatoma. These polymers take advantage of endothelial permeability as the drug carrying polymers are trapped in tumors and then taken up by tumor cells. Linkages between the polymer and drug can be designed to be cleaved extracellularly or intracellularly. The drug is released inside the tumor mass while polymer/drug not delivered to tumors is renally cleared from the body. Data generated in animal studies have shown that the polymer/drug complexes are far less toxic than free drug alone and that greater efficacy can be achieved. Thus, these polymer complexes have demonstrated significant improvement in the therapeutic index of anti-cancer drugs, including, for example, platinum.

Vitamin Mediated Targeted Delivery Technology

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Most drugs are effective only when they reach a certain minimum concentration in the region of disease, yet are well distributed throughout the body contributing to undesirable side effects. It is therefore advantageous to alter the natural biodistribution of a drug to have it more localized where it is needed. Our vitamin mediated targeted delivery technology utilizes the fact that in many diseases where there is rapid growth and/or cell division, the demand for certain vitamins increases. By coupling the drug to an appropriate vitamin, the vitamin serves as a carrier to increase the amount of drug at the disease site relative to its normal distribution.

One application of this technology is in tumor targeting. The use of cytotoxic drugs is one of the most common methods for treating a variety of malignancies including solid and non-solid tumors. The drawbacks of chemotherapeutic treatments, which include tumor resistance, cancer relapse and toxicity from severe damage to healthy tissues, has fuelled a scientific quest for novel treatments that are specifically targeted to malignant cells thus reducing damage to collateral tissues.

The design of targeted therapies involves exploitation of the difference between the structure and function of normal cells compared with malignant cells. Differences include the increased levels of surface molecules on cancer cells, which makes them more sensitive to treatment regimes that target surface molecules and differences in blood supply within and around tumor cells compared with normal cells.

Two basic types of targeting approaches are utilized, passive tumor targeting and active tumor targeting.

- passive tumor targeting involves transporting anti-cancer agents through the bloodstream to tumor cells using a “carrier” molecule. Many different carrier molecules, which can take a variety of forms (micelles, nanoparticles, liposomes and polymers), are being investigated as each provides advantages such as specificity and protection of the anti-cancer drug from degradation due to their structure, size (molecular weights) and particular interactions with tumor cells. Our polymer platinate program is a passive tumor targeting technology.
- active tumor targeting involves attaching an additional fragment to the anticancer drug and the carrier molecule to create a new “targeted” agent that will actively seek a complementary surface molecule to which it binds (preferentially located on the exterior of the tumor cells). The theory is that the targeting of the anti-cancer agent through active means to the affected cells should allow more of the anti-cancer drug to enter the tumor cell, thus amplifying the response to the treatment and reducing the toxic effect on bystander, normal tissue.

Examples of active targeting fragments include antibodies, growth factors and vitamins. Our scientists have specifically focused on using vitamin B12 and folate to more effectively target anti-cancer drugs to solid tumors.

It has been known for some time that vitamin B12 and folic acid are essential for tumor growth and as a result, receptors for these vitamins are up-regulated in certain tumors. Vitamin B12 receptor over-expression occurs in breast, lung, leukemic cells, lymphoma cells, bone, thyroid, colon, prostate and brain cancers and some other tumor lines, while folate receptor over-expression occurs in breast, lung, ovarian, endometrial, renal, colon, brain and cancers of myeloid hemopoietic cells and methotrexate-sensitive tumors.

Vitamin Mediated Oral Delivery Technology

Oral delivery is the preferred method of administration of drugs where either long-term or daily use (or both) is required. However many therapeutics, including peptide and protein drugs, are poorly absorbed when given orally. With more and more peptide and protein based biopharmaceuticals entering the market, there is an increasing need to develop an effective oral delivery system for them, as well as for long-standing injected drugs such as insulin.

The difficulty in administering proteins orally is their susceptibility to degradation by digestive enzymes, their inability to cross the intestinal wall and their rapid excretion by the body. Over the years, many different methodologies for making protein drugs available orally have been attempted. Most of the oral protein delivery technologies involve protecting the protein degradation in the intestine. More recently, strategies have been developed that involve attaching the protein or peptide to a molecule that transports the protein across the gut wall. However, the field of oral drug delivery of proteins and peptides has yet to achieve successful commercialization of

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a product (although positive results have been achieved in early clinical trials for some products under development).

Many pharmaceutically active compounds such as proteins, peptides and cytotoxic agents cannot be administered orally due to their instability in the gastrointestinal tract or their inability to be absorbed and transferred to the bloodstream. A technology that would allow many of these actives to be taken orally would greatly enhance their acceptance and value. Several technologies for the protection of sensitive actives in the gastro-intestinal tract and/or enhancement of gastro-intestinal absorption have been explored and many have failed.

Our proprietary technology for oral drug delivery utilizes the body's natural vitamin B12 (VB12) transport system in the gut. The absorption of VB12 in the intestine occurs by way of a receptor-mediated endocytosis. Initially, VB12 binds to intrinsic factor (IF) in the small intestine, and the VB12-IF complex then binds to the IF receptor on the surface of the intestine. Receptor-mediated endocytosis then allows the transport of VB12 across the gut wall. After binding to another VB12-binding protein, transcobalamin II (TcII), VB12 is transferred to the bloodstream.

Our scientists discovered that VB12 will still be transported by this process even when drugs, macromolecules, or nanoparticles are coupled to VB12. Thus VB12 serves as a carrier to transfer these materials from the intestinal lumen to the bloodstream. For drugs and macromolecules that are stable in the gastro-intestinal tract, the drug or macromolecule can be coupled directly (or via a linker) to VB12. If the capacity of the VB12 transport system is inadequate to provide an effective blood concentration of the active, transport can be amplified by attaching many molecules of the drug to a polymer, to that VB12 is also attached. A further option, especially for drugs and macromolecules that are unstable in the intestine, is to formulate the drug in a nanoparticle which is then coated with VB12. Once in the bloodstream, the active is released by diffusion and/or erosion of the nanoparticle. Utilization of nanoparticles also serves to 'amplify' delivery by transporting many molecules at one time due to the inherently large surface area.

Our proprietary position in this technology involves the conjugation of vitamin B12 and/or folic acid (or their analogs) to a polymer to which is also attached the drug to be delivered, or attached to a nanoparticle in which the drug is incorporated. Since many molecules of the drug are attached to a single polymer strand, or are incorporated in a single nanoparticle, disease targeting is amplified compared to simpler conjugates involving one molecule of the vitamin with one drug molecule. However, in situations when such a simple conjugate might be preferred, our patents also encompass these VB12-drug conjugates.

Bioerodible Cross-Linker Delivery Technology

Our scientists have developed a novel series of bioerodible cross-linkers that have the potential to be utilized with hydrogels in a number of drug delivery applications as well as several non-pharmaceutical applications. Hydrogels are very large molecules with complex three-dimensional structures capable of storing either small molecule drugs or much larger peptide and protein therapeutics. These molecules are stored within the matrix of the hydrogel. Most hydrogels are not bioerodible, therefore they deliver their payload of drug by diffusion of these molecules through the interconnecting chambers of the hydrogel. Once all of the drug has been delivered, non-bioerodible hydrogels remain in the body (unless surgically removed) as they cannot be broken down and eliminated. By comparison, our hydrogels possess bioerodible linking groups with well-defined rates of degradation in biological systems, and so release their payload of drugs by both diffusion and erosion of the hydrogel matrix. By selecting linkers with appropriate degradation rates, much greater control of drug release rates can be achieved. Once the drug has been released, erosion of the hydrogel continues until no solid hydrogel remains, eliminating the need to use an additional procedure to remove the drug delivery device. The hydrogel erodes to form much smaller water-soluble fractions which are readily eliminated from the body.

A number of possible drug delivery systems may be able to be developed using our bioerodible cross-linker technology, ranging from nanoparticles for intravenous administration, to larger devices which may be implanted, wound packaging materials, medicated and non-medicated for decubitus and vascular ulcers, medicated films and gels for topical applications, burn dressing and dressing for skin donor sites.

Mucoadhesive Disc Technology

Treatment of oral conditions generally relies upon the use of medications formulated as gels and pastes, which are applied to lesions in the mouth. The duration of effectiveness of these medications is typically short because the applied dose is worn away through the mechanical actions of speaking, eating, and tongue movement, and is washed away by saliva flow. To address these problems, we developed a mucoadhesive film product that we believe is novel, cost-effective, commercially-viable and is bioerodible. This technology, known as OraDisc™, comprises a multi-layered film having an adhesive layer, a pre-formed film layer, and a coated backing layer. Depending upon the intended application, a pharmaceutically active compound can be formulated within any of these layers, providing for a wide range of potential applications. The disc is simply applied by pressing it against the inner surface of the mouth. The disc stays in place, eroding over a period of time, so that subsequent removal is unnecessary. The disc delivers the drug over a period of time controlled by the rate of erosion of the disc, which is in turn controlled by the formulation of the backing layer.

OraDisc™ was initially developed as a drug delivery system to treat canker sores with the same active ingredient (amlexanox) that is used in Aphthasol®. We anticipate that higher amlexanox concentrations will be achieved at the disease site, increasing the effectiveness of the product, called OraDisc™ A.

We have continued to develop the OraDisc™ technology, and we have generated or are exploring additional prototype drug delivery products, including those for pain palliation in the oral cavity, gingivitis, cough and cold treatment, breath freshener, tooth whitening and other dental applications.

Hydrogel Particle Aggregate Technology

Our hydrogel particle aggregate technology provides unique materials with a broad range of properties and potential applications. While a conventional bulk hydrogel is an “infinite” network of loosely cross-linked hydrophilic polymers that swells when placed in polar solvents, we have discovered that a variety of unique biomaterials can be formed through the aggregation of hydrogel nano or micro-particles. This concept takes advantage of the inherent biocompatibility of hydrogels while overcoming problems with local stress and strain, which cause bulk hydrogels to shear. Unlike bulk hydrogels, these hydrogel particle aggregates are shape retentive, can be extruded or molded and offer properties suitable for use in a variety of in vivo medical devices, and in novel drug delivery systems, by providing tailored regions of drug incorporation and release. The polymers used in the hydrogel particle aggregate technology have been extensively researched by the academic and scientific community and commercialized into several major medical products. They are generally accepted as safe, non-toxic and biocompatible.

This technology utilizes the inherent physical attractive forces between nanoparticles themselves and between nanoparticles and a polar solvent such as water. These particles form bulk materials that can have the same size as infinite bulk networks but allow chemical variability and much greater resistance to permanent mechanical deformation. The aggregate demonstrates many physical properties identical to those of a bulk hydrogel. However, there are important differences between aggregates and bulk materials. For example, “tough” elastomeric hydrogels used in tissue engineering constructs typically fail catastrophically when placed under high strain or shear forces. As the network begins to fail under stress, the material physically breaks down. Hydrogel nanoparticle aggregates exhibit superior performance compared to bulk materials under stress as the nanoparticles can slip past each other allowing local deformation and repair.

Another major advantage of the hydrogel particle aggregate technology is the ability to tailor the degradation of hydrogel nanoparticles and hydrogel nanoparticle aggregates. Our degradable cross-linker technology can be incorporated into the hydrogel nanoparticles allowing the formation of nanoparticles containing drug with degradation and drug release at specific rates. Potentially, aggregate materials can be formulated containing mixtures of particles degrading at different rates, and/or formulations containing different drugs each released at a predefined controlled rate.

A second level of controlled degradation is provided by the ability to tailor the rate of particle erosion from the physically coalesced aggregate. The hydrogel can be formulated such that the aggregate is extremely tough and resilient, or formulated so that it can slowly erode at controlled rates. This is achieved through simple

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compositional changes during nanoparticle synthesis. The spaces between nanoparticles, or holes in the lattice, can be tailored by varying the nanoparticle size. These spaces have been used to encapsulate proteins during aggregate formation. The ability to trap a wide range of bioactive compounds between these particles in the presence of water solutions offers another major advantage, since this media is less deleterious to many compounds than solvents typically used with other drug delivery materials. These aggregates can easily be designed to remain together indefinitely in vivo, or break apart at specific rates. Pharmaceutically-active compounds trapped in a non-degradable aggregate will be released from the hydrogel by diffusion, while release is controlled by both diffusion and rate of erosion in degradable aggregates.

This technology has a variety of potential applications, such as in-dwelling medicated catheters, medicated stents, artificial discs, tissue scaffold and controlled-release drug delivery systems. We continue to develop the technology and specific applications utilizing this technology, while seeking to establish collaborations and partnerships to explore other applications.

Residerm® Topical Delivery Technology

We have granted a license to ProStrakan for the development of compounds that utilize our zinc technology. The use of zinc ions to formulate topical products produces a reservoir of drug in the skin to increase the effectiveness of topically applied products and to reduce toxicity. There are many localized disease conditions, which are effectively treated by topical application of suitable pharmaceutical agents. In order for such treatments to be maximally effective, it is necessary that as much of the active agent as possible be absorbed into the skin where it can make contact with the disease condition in the dermal tissue without being lost by rubbing off on clothing or evaporation. At the same time, the agent must not penetrate so effectively through the skin that it is absorbed into the systemic circulation. This latter factor is especially important in order to minimize unwanted side effects of the pharmacologically active agent. The ideal vehicle for topically applied pharmaceuticals is one that can rapidly penetrate the skin and produce a “reservoir effect” in the skin or mucous membranes. Such a reservoir effect can be produced by complexing of suitable pharmaceutical agents with zinc ions, by an as yet unknown mechanism. This “reservoir effect” is defined as an enhancement of the skin or membrane’s ability to both absorb and retain pharmacological agents, that is:

- to increase skin or membrane residence time;
- to decrease drug transit time; and
- to reduce transdermal flux.

A number of compounds are known to enhance the ability of pharmacologically active agents to penetrate the skin, but have the disadvantage of allowing rapid systemic dispersion away from the site of disease. Many topical agents, such as the retinoids used in the treatment of acne, and methotrexate, used in the treatment of psoriasis, are systemically toxic. There is, therefore, a need for a method of enhancing the ability of such agents to penetrate the skin so that a lesser total dosage may be used, while at the same time their ability to move from the skin to the systemic circulation is minimized.

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Research Projects, Products and Products in Development

ACCESS DRUG PORTFOLIO

Compound	Originator	Licensing Partner	Indication	FDA Filing	Clinical Stage ⁽¹⁾
Cancer Polymer Platinite (AP5346) ⁽²⁾	Access – U London	—	Ovarian, Colorectal cancer	Clinical Development ⁽⁵⁾	Phase I
Amlexanox ⁽³⁾	Takeda	ProStrakan, Zambon Esteve, Meda, Mipharm, Paladin	Aphthous ulcers	NDA	Approved
OraDisc™ Amlexanox ⁽³⁾ Biodegradable Polymer Disc	Access	Discus Dental, ProStrakan, Zambon Esteve, Meda, Mipharm, Paladin	Aphthous ulcers	NDA	Approved
Residerm® A Zinc Clindamycin ⁽⁴⁾	Access	ProStrakan, Fujisawa	Acne	PLA ⁽⁶⁾	Approved ⁽⁷⁾
OraDisc™ Benzocaine	Access	—	Oral pain	OTC	N/A
Vitamin Medicated Delivery Oral Delivery System	Access	— ⁽⁸⁾	Various	Research	Pre-Clinical
Vitamin Targeted Therapeutics	Access	—	Anti-tumor	Research	Pre-Clinical

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

(2) Licensed from the School of Pharmacy, The University of London. Subject to royalty and milestone payments.

(3) Acquired from GlaxoSmithKline – Block Drug Company. Amlexanox licensing agreements executed with the following parties for the prevention and treatment of aphthous ulcers:

- Discus Dental for U.S. marketing rights for Amlexanox and OraDisc A.
- ProStrakan Limited for UK and Ireland manufacturing and marketing rights.
- Zambon Group for France, Germany, Holland, Belgium, Luxembourg, Switzerland, Brazil, Columbia and Italy manufacturing and marketing rights.
- Laboratories Dr. Esteve SA for Spain, Portugal and Greece manufacturing and marketing rights.
- Mipharm SpA for Italy manufacturing and marketing rights.
- Meda, AB for Scandinavia, the Baltic states and Iceland marketing rights.
- Paladin Labs Inc. for Canada manufacturing and marketing rights.
- EpiTan, Ltd. for Australia and New Zealand marketing rights.
- Orient Europharma. Co. Ltd. for Taiwan, Hong-Kong, Malaysia, Philippines, Thailand and Singapore marketing rights.

(4) Licensed worldwide manufacturing and marketing rights to ProStrakan who sublicensed to:

- Fujisawa GmbH for continental Europe marketing rights.
- EpiTan for Australia and New Zealand marketing rights.
- Hyundai for Korea marketing rights.

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- Taro Pharmaceuticals for Israel marketing rights.
- Biosintetica for Brazil marketing rights.
- Various companies for other smaller countries for marketing rights.

(5) Clinical studies being conducted in Europe and US.

(6) United Kingdom equivalent of an NDA.

(7) Marketing approval received from the Medicines Control Agency in the U.K. and product launched in March 2002. In addition there the product has been extensively approved throughout the European Union.

(8) Research collaboration agreement with Celltech Group plc.

We begin the product development effort by screening and formulating potential product candidates, selecting an optimal active and formulation approach and developing the processes and analytical methods. Pilot stability, toxicity and efficacy testing are conducted prior to advancing the product candidate into formal preclinical development. Specialized skills are required to produce these product candidates utilizing our technology. We have a core internal development capability with significant experience in developing these formulations.

Once the product candidate has been successfully screened in pilot testing, our scientists, together with external consultants, assist in designing and performing the necessary preclinical efficacy, pharmacokinetic and toxicology studies required for IND submission. External investigators and scaleup manufacturing facilities are selected in conjunction with our consultants. The initial Phase I and Phase II studies are conducted by institutions and investigators supervised and monitored by our employees and contract research organizations. We do not plan to have an extensive clinical development organization as we plan to have the advance phases of this process conducted by a development partner. Should we conduct Phase III clinical studies we expect to engage a contract research organization to perform this work.

We contract with third party contract research organizations to complete our large clinical trials and for data management of all of our clinical trials. Generally, we manage the smaller Phase I and II trials ourselves. Currently, we have one Phase I trial in process, one planned Phase I trials and two Phase II trials planned for this year.

With all of our product development candidates, we cannot assure you that the results of the in vitro or animal studies are or will be indicative of the results that will be obtained if and when these product candidates are tested in humans. We cannot assure you that any of these projects will be successfully completed or that regulatory approval of any product will be obtained.

We expended approximately \$5,417,000, \$6,096,000 and \$7,024,000 on research and development during the years 2004, 2003 and 2002, respectively.

Patents

We believe that the value of technology both to us and to our potential corporate partners is established and enhanced by our broad intellectual property positions. Consequently, we have already been issued and seek to obtain additional U.S. and foreign patent protection for products under development and for new discoveries. Patent applications are filed with the U.S. Patent and Trademark Office and, when appropriate, with the Paris Convention's Patent Cooperation Treaty (PCT) Countries (most major countries in Western Europe and the Far East) for our inventions and prospective products.

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

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a tumor site. The patents and patent applications also include methods for improving the pharmaceutical properties of platinum compounds.

One U.S. and two European patents have issued and one European patent is pending for the use of zinc as a pharmaceutical vehicle for enhancing the penetration and retention of drug in the skin. The patents and patent application cover the method of inducing a reservoir effect in skin and mucous membranes to enhance penetration and retention of topically applied therapeutic and cosmetic pharmacologically active agents. The patents and patent application also relate to topical treatment methods including such reservoir effect enhancers and to pharmaceutical compositions containing them.

We have one U.S. patent and one European patent is pending for our bioerodible cross-linker technology. A number of possible drug delivery systems can be developed using our bioerodible cross-linker technology, ranging from nanoparticles for intravenous administration, to larger devices which may be implanted, wound packaging materials, medicated and non-medicated for decubitus and vascular ulcers, medicated films and gels for topical applications, burn dressing and dressing for skin donor sites.

We have one U.S. patent and have filed one U.S. and one European patent application for our OraDisc™ technology. This oral delivery vehicle potentially overcomes the difficulties encountered in using conventional paste and gel formulations for conditions in the mouth. Utilizing this technology, we anticipate that higher drug concentrations will be achieved at the disease site increasing the effectiveness of the product.

We have filed two U.S. patent applications and two European patent applications for our mucoadhesive liquid technology. Our patent applications cover a range of products utilizing our mucoadhesive liquid technology for the management of the various phases of mucositis.

We have filed two U.S. patent applications and two European patent applications for our hydrogel particle aggregate technology. Our patent applications have a variety of potential applications, such as in-dwelling medicated catheters, medicated stents, artificial discs, tissue scaffold and controlled-release drug delivery systems.

Through our Access Pharmaceuticals Australia Pty. Limited subsidiary we have three patented targeted therapeutic technologies:

- folate conjugates of polymer therapeutics, to enhance tumor delivery by targeting folate receptors, which are upregulated in certain tumor types with two U.S. and two European patent applications;
- the use of vitamin B12 to target the transcobalamin II receptor which is upregulated in numerous diseases including cancer, rheumatoid arthritis, certain neurological and autoimmune disorders with two U.S. patents and three U.S. and four European patent applications; and
- oral delivery of a wide variety of molecules which cannot otherwise be orally administered, utilizing the active transport mechanism which transports vitamin B12 into the systemic circulation with six U.S. patents and two European patents and one U.S. and one European patent application.

We also have a patent for amlexanox and the worldwide rights, excluding Japan, for the use of amlexanox for oral and dermatological use.

We have a strategy of maintaining an ongoing line of patent continuation applications for each major category of patentable carrier and delivery technology. By this approach, we are extending the intellectual property protection of our basic targeting technology and initial agents to cover additional specific carriers and agents, some of which are anticipated to carry the priority dates of the original applications.

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Government Regulation

We are subject to extensive regulation by the federal government, principally by the FDA, and, to a lesser extent, by other federal and state agencies as well as comparable agencies in foreign countries where registration of products will be pursued. Although a number of our formulations incorporate extensively tested drug substances, because the resulting formulations make claims of enhanced efficacy and/or improved side effect profiles, they are expected to be classified as new drugs by the FDA.

The Federal Food, Drug and Cosmetic Act and other federal, state and foreign statutes and regulations govern the testing, manufacturing, safety, labeling, storage, shipping and record keeping of our products. The FDA has the authority to approve or not approve new drug applications and inspect research, clinical and manufacturing records and facilities.

Among the requirements for drug approval and testing is that the prospective manufacturer's facilities and methods conform to the FDA's Code of Good Manufacturing Practices regulations, which establish the minimum requirements for methods to be used in, and the facilities or controls to be used during, the production process. Such facilities are subject to ongoing FDA inspection to insure compliance.

The steps required before a pharmaceutical product may be produced and marketed in the U.S. include preclinical tests, the filing of an IND with the FDA, which must become effective pursuant to FDA regulations before human clinical trials may commence, numerous phases of clinical testing and the FDA approval of a NDA prior to commercial sale.

Preclinical tests are conducted in the laboratory, usually involving animals, to evaluate the safety and efficacy of the potential product. The results of preclinical tests are submitted as part of the IND application and are fully reviewed by the FDA prior to granting the sponsor permission to commence clinical trials in humans. All trials are conducted under International Conference on Harmonization, or ICH, good clinical practice guidelines. All investigator sites and sponsor facilities are subject to FDA inspection to insure compliance. Clinical trials typically involve a three-phase process. Phase I, the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages and in some indications such as cancer and HIV, as preliminary evidence of efficacy in humans. Phase II involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. When a product is found safe, an initial efficacy is established in Phase II, it is then evaluated in Phase III clinical trials. Phase III trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit to risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA for approval to commence commercial sales.

The process of forming the requisite testing, data collection, analysis and compilation of an IND and an NDA is labor intensive and costly and may take a protracted time period. In some cases, tests may have to be redone or new tests instituted to comply with FDA requests. Review by the FDA may also take considerable time and there is no guarantee that an NDA will be approved. Therefore, we cannot estimate with any certainty the length of the approval cycle.

We are also governed by other federal, state and local laws of general applicability, such as laws regulating working conditions, employment practices, as well as environmental protection.

Competition

The pharmaceutical and biotechnology industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and other product areas where we may develop and market products in the future. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technical resources than are available to us. Additionally, many of our potential competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our product lines. Our potential products could be rendered obsolete or made uneconomical by the

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development of new products to treat the conditions to be addressed by our developments, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our potential competitors. Our business, financial condition and results of operation could be materially adversely affected by any one or more of such developments. We cannot assure you that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or with the assistance of major health care companies in areas where we are developing product candidates. We are aware of certain development projects for products to treat or prevent certain diseases targeted by us, the existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed by us.

The principal competitors in the polymer area are Cell Therapeutics, Daiichi, Enzon and Inhale which are developing alternate drugs in combination with polymers. We believe we are the only company conducting clinical studies in the polymer drug delivery of platinum compounds. We believe that the principal current competitors to our polymer targeting technology fall into two categories: monoclonal antibodies and liposomes. We believe that our technology potentially represents a significant advance over these older technologies because our technology provides a system with a favorable pharmacokinetic profile.

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

Products developed from our Residerm® technology will compete for a share of the existing market with numerous products which have become standard treatments recommended or prescribed by dermatologists. Zindaclin®, which is the first product developed utilizing our Residerm® technology, will compete with products including Benzamycin, marketed by a subsidiary of Aventis; Cleocin-T and a generic topical clindamycin, marketed by Pharmacia; Benzac, marketed by a subsidiary of L'Oreal; and Triaz, marketed by Medicis Pharmaceutical Corp.

Aphthasol® is the only clinically proven product to accelerate the healing of canker sores. There are numerous products, including prescription steroids such as Kenalog in OraBase, and many over-the-counter pain relief formulations that incorporate a local anesthetic used for the treatment of this condition.

In the area of advanced drug delivery, which is the focus of our early stage research and development activities, a number of companies are developing or evaluating enhanced drug delivery systems. We expect that technological developments will occur at a rapid rate and that competition is likely to intensify as various alternative delivery system technologies achieve similar if not identical advantages.

Even if our products are fully developed and receive required regulatory approval, of which there can be no assurance, we believe that our products can only compete successfully if marketed by a company having expertise and a strong presence in the therapeutic area. Consequently, we do not currently plan to establish an internal marketing organization. By forming strategic alliances with major and regional pharmaceutical companies, management believes that our development risks should be minimized and that the technology potentially could be more rapidly developed and successfully introduced into the marketplace.

Employees

As of March 15, 2005, we had 35 full time employees, 17 of whom have advanced scientific degrees. Of these employees, 31 are engaged in, or directly supporting research and development activities and four are in business administration positions. We have never experienced employment-related work stoppages and consider that we maintain good relations with our personnel. In addition, to complement our internal expertise, we have contracts with scientific consultants, contract research organizations and university research laboratories that specialize in

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various aspects of drug development including clinical development, regulatory affairs, toxicology, process scale-up and preclinical testing.

Web Availability

We make available free of charge through our web site, www.accesspharma.com, our annual reports on Form 10-K and other reports required under the Securities and Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are filed with, or furnished to, the Securities and Exchange Commission as well as certain of our corporate governance policies, including the charters for the Board of Director's audit, compensation and nominating and corporate governance committees and our code of ethics, corporate governance guidelines and whistleblower policy. We will provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207 attn: Investor Relations.

MANAGEMENT

The following table sets forth the names, ages, and titles of each of our directors and executive officers as of May 15, 2005:

<u>Name</u>	<u>Age</u>	<u>Title</u>
J. Michael Flinn	71	Chairman of the Board
Rosemary Mazanet, M.D., Ph.D	49	Acting Chief Executive Officer, Director
Stuart M. Duty	40	Director
Stephen B. Howell, M.D.	60	Director
Max Link, Ph.D.	64	Director
Herbert H. McDade, Jr.	78	Director
John J. Meakem, Jr.	68	Director
David P. Nowotnik, Ph.D.	56	Senior Vice President Research & Development
Stephen B. Thompson	51	Vice President, Chief Financial Officer, Treasurer

Mr. J. Michael Flinn has served as one of our directors since 1983. Mr. Flinn is Chairman of the Board and a member of the Compensation Committee of the Board. Since 1970, he has been an investment counselor and was a consultant to the Operations Group of United Asset Management. From 1970 to 1996 he was a principal with the investment counseling firm of Sirach Capital Management, Inc. He assisted in the management of pension, profit sharing, individual, corporate and foundation accounts totaling over \$7.0 billion. He serves as a board member of Lonesome Dove Petroleum.

Rosemary Mazanet, M.D., Ph.D. Dr. Mazanet currently serves as Chief Executive Officer of Breakthrough Therapeutics, LLC, a privately held development stage biotechnology company. From June 1998 to February 2004, Dr. Mazanet served as Chief Scientific Officer and a General Partner of Oracle Partners, L.P., a healthcare investment firm. As Sr. Director of Clinical Research at Amgen in the early and mid 1990s, she was responsible for the submission of corporate INDs, the registration strategy and conduct of Phase I, II and III clinical trials. Dr. Mazanet also serves as an independent director at GTx, Inc (Nasdaq: GTXI) and is a trustee at the University of Pennsylvania, School of Medicine where she received her M.D. and Ph.D. Dr. Mazanet was trained as an oncologist in the Harvard Medical System where she was also a faculty member.

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Mr. Stuart M. Duty has served as one of our directors since November 2002. Mr. Duty is also a member of the Audit & Finance Committee of the Board. Mr. Duty is currently a Partner at Oracle Partners, L.P. Prior to joining Oracle Partners, L.P. he held senior healthcare investment banking positions, most recently, from 1999 to 2001, as the Co-Head of Healthcare Investment Banking at US Bancorp Piper Jaffray. From 1993 to 1999 he was Managing Director at NationsBank Montgomery Securities. In addition to his investment banking experience, Mr. Duty has worked in the biotechnology industry in a business development capacity.

Stephen B. Howell, M.D. has served as one of our directors since 1996. Dr. Howell is a Professor of Medicine at the University of California, San Diego, and director of the Cancer Pharmacology Program of the UCSD Cancer Center. Dr. Howell is a recipient of the Milken Foundation prize for his contributions to the field of cancer chemotherapy. He has served on the National Research Council of the American Cancer Society and is on the editorial boards of multiple medical journals. Dr. Howell founded DepoTech, Inc. and served as a member of its board of directors from 1989 to 1999. Dr. Howell served on the board of directors of Matrix Pharmaceuticals from 2000 to 2002. Dr. Howell received his AB at the University of Chicago and his MD from Harvard Medical School.

Max Link, Ph.D. has been one of our directors since 1996. Dr. Link is also a Chairman of the Audit & Finance Committee of the Board and a member of the Compensation Committee of the Board. He has held a number of executive positions with pharmaceutical and health care companies. Most recently, from March 2001 until August 2003, Dr. Link served as Chairman and CEO of Centerpulse, Ltd. (now a part of Zimmer Holdings, Inc.). From May 1993 until June 1994, he served as Chief Executive Officer of Corange Limited. Prior to joining Corange, Dr. Link served in a number of positions with Sandoz Pharma Ltd., including Chief Executive Officer, from 1987 until April 1992, and Chairman, from April 1992 until May 1993. Dr. Link currently serves on the board of directors of six other publicly-traded life science companies: Alexion Pharmaceuticals, Inc., Cell Therapeutics, Inc., Celsion Corporation, Inc., Discovery Laboratories, Inc., Human Genome Sciences, Inc., and Protein Design Labs, Inc. Dr. Link received his Ph.D. in Economics from the University of St. Gallen in 1970.

Mr. Herbert H. McDade, Jr. was elected to be one of our directors in 1988, and was Chairman of the Board until 2004. He is Chairman of the Compensation Committee of the Board. In February 1989, he was elected Vice-Chairman of the Board and Chief Executive Officer and served in such positions until 1996. In June 1989, he was elected Chairman of the Board and Treasurer in addition to his responsibilities as Chief Executive Officer, and from 1990 to January 1996 he was our President. In addition, he also serves on the board of Discovery Laboratories, 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 from 1979 to 1986, as President of the International Division of the Revlon Health Care Group. He was also previously associated for twenty years in various executive capacities with The Upjohn Company.

Mr. John J. Meakem, Jr. has been one of our directors since 2001. Mr. Meakem is also a member of the Audit & Finance Committee of the Board. Mr. Meakem is a private investor with portfolio holdings in innovative companies with a particular focus on healthcare. Most recently Mr. Meakem served as Chairman of the Board, President and Chief Executive Officer of Advanced Polymer Systems, Inc. from 1991 to 2000. Prior to 1991, he was Corporate Executive Vice President of Combe, Inc. and President of Combe North America. Prior to 1970, Mr. Meakem was with Vick Chemical Company, a division of Richardson Merrell Drug Corporation, for ten years as Vice President of Marketing, New Products & Acquisitions.

David P. Nowotnik, Ph.D. has been Senior Vice President Research and Development since January 2003 and was Vice President Research and Development from 1998. From 1994 until 1998, Dr. Nowotnik had been with Guilford Pharmaceuticals, Inc. in the position of Senior Director, Product Development and was responsible for a team of scientists developing polymeric controlled-release drug delivery systems. From 1988 to 1994 he was with Bristol-Myers Squibb researching and developing technetium radiopharmaceuticals and MRI contrast agents. From 1977 to 1988 he was with Amersham International leading the project which resulted in the discovery and development of Ceretec.

Mr. Stephen B. Thompson has been Vice President since 2000 and our Chief Financial Officer since 1996. From 1990 to 1996, he was Controller and Administration Manager of Access Pharmaceuticals, Inc., a private Texas corporation. Previously, from 1989 to 1990, Mr. Thompson was Controller of Robert E. Woolley, Inc., a hotel real

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estate company where he was responsible for accounting, finances and investor relations. 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.

Executive Compensation

The following table sets forth the aggregate compensation paid to our CEO and each of our other executive officers whose aggregate salary and bonus exceeded \$100,000 (the "Named Executive Officers") for services rendered in all capacities for the fiscal years ended December 31, 2004, 2003 and 2002.

Summary Compensation Table

Name and Principal Position	Annual Compensation			Long-term Compensation Awards		
	Year	Salary (1)	Bonus (2)	Restricted Stock (\$)(3)	Securities Underlying Options (#)	All Other (4) Compensation
Kerry P. Gray President and CEO	2004	\$384,449	\$ —	\$ —	100,000	\$ 11,470
	2003	366,848	130,000(5)	—	140,000	10,837
	2002	338,150	110,000(5)	105,000	160,000	9,713
David P. Nowotnik, Ph.D. Senior Vice President Research and Development	2004	\$238,995	\$ —	\$ —	25,000	\$ 6,433
	2003	226,530	24,154	20,412	35,000	6,042
	2002	212,001	20,142	19,960	50,000	5,648
Stephen B. Thompson Vice President, Chief Financial Officer	2004	\$145,260	\$ —	\$ —	15,000	\$ 3,365
	2003	138,030	14,704	12,474	20,000	3,918
	2002	129,501	12,474	12,176	30,000	3,540

(1) Includes amounts deferred under our 401(k) Plan.

(2) Includes bonuses earned in the reported year but paid in the following year.

(3) The value of all restricted stock for each named individual at December 31, 2004 is: Mr. Gray — \$118,445; Dr. Nowotnik — \$75,207; and Mr. Thompson — \$45,847.

(4) Amounts reported for fiscal years 2004, 2003, and 2002 consist of: (i) amounts we contributed to our 401(k) Plan with respect to each named individual, (ii) amounts we paid for group term life insurance for each named individual, and (iii) for Mr. Gray, premiums paid by us each year for life insurance for Mr. Gray.

(5) Mr. Gray's 2002 bonus of \$110,000 was deferred, by election of the Compensation Committee and Mr. Gray, until certain performance goals were met. Our primary goal in signing a licensing or equity agreement at certain levels was met and the bonus was paid in 2004.

The following table sets forth information concerning individual grants of stock options in 2004 to the Named Executive Officers.

Individual Option Grants In Last Fiscal Year

Name	Number of Securities Underlying Options Granted (#)	Percent of Total Options Granted to Employees in Fiscal Year (1)	Exercise Price \$ / Sh (2)	Expiration Date	Potential Realizable Value at Assumed Annual Rates of Stock Appreciation For Option Term (3)	
					5%	10%
Kerry P. Gray (4)	100,000	32%	\$ 5.85	1/23/14	\$368,000	\$932,000
David P. Nowotnik (4)	25,000	8%	\$ 5.85	1/23/14	\$ 92,000	\$233,000
Stephen B. Thompson (4)	15,000	5%	\$ 5.85	1/23/14	\$ 55,000	\$140,000

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- (1) Based on an aggregate of 314,200 options granted to employees in the 2004 fiscal year, including options granted to the named individual.
- (2) The exercise price of each grant is the closing price on the date of grant as quoted on AMEX.
- (3) Potential realizable value is based on the assumption that the price per share of our common stock appreciates at the assumed annual rate of stock appreciation for the option term. There is no assurance that the assumed 5% and 10% annual rates of appreciation (compounded annually) will actually be realized over the term of the option. The assumed 5% and 10% annual rates are set forth in accordance with the rules and regulations adopted by the SEC and do not represent our estimate of stock price appreciation.
- (4) Mr. Gray, Dr. Nowotnik and Mr. Thompson's options vest 25% after twelve months and the remaining 75% vest 2.083% monthly commencing twelve months from the date of grant and are exercisable in full 48 months after the date of grant.

Option Exercises and Year-End Value Table

The following table includes the number of shares covered by both exercisable and non-exercisable stock options held by the Named Executive Officers as of December 31, 2004. Also reported are the values of "in-the-money" stock options which represent the positive spread between the exercise price of any such existing stock options and the year-end price of our common stock.

Aggregated Option Exercises In Last Fiscal Year And Fiscal Year-End Option Values

Name	Number of Shares Acquired On Exercise #	Value Realized (\$)	Number of Securities Underlying Unexercised Options At Fiscal Year End Exercisable/ Unexercisable	Value of Unexercised In- The-Money Options (\$) ⁽¹⁾ At Fiscal Year End Exercisable/ Unexercisable
Kerry P. Gray	—	—	1,257,083 / 222,917	\$ 936,000 / \$90,000
David P. Nowotnik, Ph.D.	—	—	201,146 / 58,854	\$ 181,000 / \$28,000
Stephen B. Thompson	—	—	115,208 / 34,792	\$ 103,000 / \$16,000

- (1) On December 31, 2004, the closing price of our common stock as quoted on AMEX was \$3.54.

Equity Compensation Plan Information

The following table sets forth information as of December 31, 2004 about shares of our common stock outstanding and available for issuance under our existing equity compensation plans.

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Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders			
1995 Stock Awards Plan	2,182,181	\$ 3.76	129,780
2001 Restricted Stock Plan	126,474	—	38,762
Equity compensation plans not approved by security holders			
2000 Special Stock Option Plan	500,000	\$ 2.50	—
Total	<u>2,808,655</u>	<u>\$ 3.37</u>	<u>168,542</u>

Compensation Pursuant to Agreements and Plans

Employment Agreements

On May 11, 2005, we announced that Kerry P. Gray resigned as our President and Chief Executive Officer, effective as of May 10, 2005. Mr. Gray resigned from our Board of Directors and from all other positions held with us, effective as of May 10, 2005. We entered into a Separation Agreement with Mr. Gray dated as of May 10, 2005. Pursuant to the terms of the Separation Agreement, Mr. Gray has agreed to provide us with certain post-termination assistance. He also agreed to maintain the confidentiality of our proprietary information and to a customary mutual release of claims with us. The Separation Agreement provides for an immediate cash payment to Mr. Gray of \$225,000 and payments of \$33,333.33 each month for a period of 18 months, which payments are secured by a lien on our assets and in addition, we could be required to issue and the holders would have the ability to sell up to 2,891,723 shares of our common stock. We are required to issue 3,500 shares of our common stock to Mr. Gray each month for a period of 18 months following May 10, 2005. The Separation Agreement also provides that all of Mr. Gray's outstanding stock options and shares of restricted stock immediately and fully vested and options remain exercisable for a period of two years.

On May 11, 2005, we announced that Rosemary Mazanet, M.D., Ph.D, has been named by the Board of Directors as our Acting Chief Executive Officer, effective as of May 11, 2005. The agreement is memorialized in a Letter Agreement with us, dated May 10, 2005. Dr. Mazanet's title will be Acting Chief Executive Officer and she will report directly to, and be subject to the direction of, our Board of Directors. Dr. Mazanet will be paid a weekly salary of \$7,500 for the duration of the Letter Agreement, and she was granted a non-qualified stock option of 30,000 shares of our common stock, with an exercise price equal to the last sale price on May 11, 2005. Dr. Mazanet's option will vest monthly over a six month period. The Letter Agreement also grants Dr. Mazanet similar employee benefits as our other executive officers, D&O insurance coverage and a signing bonus of \$30,000. The Letter Agreement provides for additional option or cash grants based on milestones to be agreed upon by Dr. Mazanet and our Board of Directors.

We are party to an employment agreement with David P. Nowotnik, Ph.D., our Senior Vice President, Research and Development, which expires November 16, 2005 and which thereafter may be automatically renewed for successive one-year periods. Under this agreement, Dr. Nowotnik is currently entitled to receive an annual base salary of \$241,980, subject to adjustment by the Board. Dr. Nowotnik is eligible to participate in all of our employee benefit programs available to executives. Dr. Nowotnik is also eligible to receive:

- a bonus payable in cash and common stock related to the attainment of reasonable performance goals specified by the Board;
- stock options at the discretion of the Board;
- long-term disability insurance to provide compensation equal to at least \$60,000 annually; and
- term life insurance coverage of \$242,000.

Dr. Nowotnik is entitled to certain severance benefits in the event that we terminate his employment without cause or if Dr. Nowotnik terminates his employment following a change of control. In the event that we terminate the employment agreement for any reason, other than for cause, Dr. Nowotnik would receive the salary due for six months. We will also continue benefits for such period. In the event that Dr. Nowotnik's employment is terminated

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within six months following a change in control or by Dr. Nowotnik upon the occurrence of certain events following a change in control, Dr. Nowotnik would receive twelve months salary and his stock options shall become immediately exercisable. We will also continue payment of benefits for such period.

Board Committees

The standing committees of the Board are the Audit and Finance Committee, the Compensation Committee and the Nominating and Corporate Governance Committee.

The Audit and Finance Committee presently is composed of three directors, Max Link, Ph.D., Stuart M. Duty and John J. Meakem, Jr., each of whom the Board has determined is independent under applicable SEC and AMEX rules and regulations. The Board has determined that Dr. Link is qualified to be an "audit committee financial expert" under applicable rules and regulations of the SEC. The Audit and Finance Committee is governed by a charter, which is available on our website at www.accesspharma.com and delegates to the Audit and Finance Committee, among other things, the responsibility to engage the independent auditors, review the audit fees, supervise matters relating to audit functions and review and set internal policies and procedure regarding audits, accounting and other financial controls.

The Compensation Committee presently is composed of three directors, Herbert H. McDade, Jr., J. Michael Flinn and Max Link, each of whom the Board has determined is independent under applicable AMEX rules and regulations. Responsibilities of this committee include approval of remuneration arrangements for our executive officers, review and approval of compensation plans relating to executive officers and directors, including grants of stock options under our 1995 Stock Awards Plan and 2000 Special Stock Option Plan, and other benefits and general review of our employee compensation policies. The charter of the Compensation Committee is available on our website at www.accesspharma.com.

The Nominating and Corporate Governance Committee is composed of three directors, Stuart M. Duty, John J. Meakem and Max Link, Ph.D., each of whom the Board has determined is independent under applicable AMEX rules and regulations. The Nominating and Corporate Governance Committee is responsible for, among other things, considering potential Board members, making recommendations to the full Board as to nominees for election to the Board, assessing the effectiveness of the Board and implementing our corporate governance guidelines. The charter of the Nominating and Corporate Governance Committee is available on our website at www.accesspharma.com.

Compensation Committee Interlocks And Insider Participation

The members of the Compensation Committee of the Board are Mr. McDade, Mr. Flinn and Dr. Link. The Compensation Committee makes recommendations to the Board regarding executive compensation matters, including decisions relating to salary and annual incentive payments and grants of stock options. None of our executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as members of our Board of Directors or our Compensation Committee.

Compensation of Directors

As of March 31, 2005, each director who is not our employee receives a quarterly fee of \$3,000 and \$1,000 per quarter per committee (aggregate for all committees) in which he/she is a member. The Chairman of the Board is paid an additional \$1,000 per quarter and the Chairman of each of the Audit and Finance and Compensation Committee is paid an additional \$500 per quarter. Each director will have \$2,000 deducted from their fee if more than one Board meeting is missed and \$1,000 deducted per committee meeting missed. In addition, we reimbursed each director, whether an employee or not, the expenses of attending board and committee meetings. Each non-employee director is also entitled to receive options to purchase 12,500 shares of our common stock on the date of each annual meeting of stockholders and options to purchase 20,000 shares of common stock when he/she is first appointed as a director.

LEGAL PROCEEDINGS

None.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

Based solely upon information made available to us, the following table sets forth certain information with respect to the beneficial ownership of our common stock as of May 15, 2005 by (i) each person who is known by us to beneficially own more than five percent of our common stock; (ii) each of our directors; (iii) each of our executive officers; and (iv) all our executive officers and directors as a group. Beneficial ownership as reported in the following table has been determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended. Except as otherwise indicated, the holders listed below have sole voting and investment power with respect to all shares of our common stock beneficially owned by them. The address of each holder listed below, except as otherwise indicated, is c/o Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207.

Security Ownership of Certain Beneficial Owners

Name	Number of Shares (1)	Percentage of Class
Dr. Rosemary Mazanet, M.D., Ph.D (2)	10,000	*
J. Michael Flinn (3)	171,337	1.0%
Stuart M. Duty (4)	20,000	*
Stephen B. Howell, M.D. (5)	155,695	1.0%
Max Link, Ph.D. (6)	72,000	*
Herbert H. McDade, Jr. (7)	87,257	1.0%
John J. Meakem, Jr. (8)	100,000	1.0%
David P. Nowotnik, Ph.D. (9)	309,767	1.9%
Stephen B. Thompson (10)	175,313	1.1%
Kerry P. Gray (11)	1,723,181	10.0%
Heartland Advisors, Inc. (12)	1,715,300	10.9%
Larry Feinberg (13)	1,954,200	11.9%
All Directors and Executive Officers as a group (consisting of 9 persons) (14)	1,101,369	6.72%

* - Less than 1%

- (1) Includes our common stock held plus all options exercisable within 60 days of May 26, 2005.
- (2) Includes presently exercisable options for the purchase of 10,000 shares of our common stock.
- (3) Including presently exercisable options for the purchase of 70,000 shares of our common stock pursuant to the 1995 Stock Option Plan.
- (4) Mr. Duty is a partner in Oracle Partners, L.P. Oracle Partners, L.P. and affiliates (Oracle Institutional Partners, L.P., Oracle Investment Management, Inc., Sam Oracle Fund, Inc., and Larry N. Feinberg) are known to beneficially own an aggregate of 1,945,200 shares of our common stock. Mr. Duty disclaims beneficial ownership of all such shares except to the extent of his pecuniary interest therein.
- (5) Including presently exercisable options for the purchase of 52,084 shares of our common stock pursuant to the 1995 Stock Option Plan and a warrant to purchase 30,000 shares of our common stock at an exercise price of \$3.00 per share, a warrant to purchase 10,000 shares of our common stock at an exercise price of \$4.91 per share, and a warrant to purchase 15,000 shares of our common stock at an exercise price of \$3.00 per share.
- (6) Including presently exercisable options for the purchase of 22,500 shares of our common stock pursuant to the 1995 Stock Option Plan.
- (7) Including presently exercisable options for the purchase of 50,000 shares of our common stock pursuant to the 1995 Stock Option Plan. Also includes 1,000 shares of our common stock owned by Thoma Corporation of which Mr. McDade is the beneficial owner.
- (8) Including presently exercisable options for the purchase of 55,000 shares of our common stock pursuant to the 1995 Stock Option Plan.
- (9) Including presently exercisable options for the purchase of 222,188 shares of our common stock pursuant to the 1995 Stock Option Plan.
- (10) Including presently exercisable options for the purchase of 127,208 shares of our common stock pursuant to the 1995 Stock Option Plan.
- (11) Kerry P. Gray, c/o Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207, beneficially owns 236,181 shares of our common stock. Mr. Gray is known to be the beneficial owner of more than five percent of our common stock. Mr. Gray's ownership includes presently exercisable options for the purchase of 1,480,000 shares of our common stock pursuant to the 1995 Stock Option Plan and the 2000 Special Stock Option Plan and 7,000 shares issuable to Mr. Gray within the next 60 days pursuant to his Separation Agreement.



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- (12) Heartland Advisors, Inc., 789 North Water Street, Milwaukee, WI 53202, beneficially owns 1,715,300 shares of our common stock. Heartland is known to be the beneficial owner of more than ten percent of our common stock. William J. Nasqovitz, as a result of his stock ownership of Heartland, could be deemed to have voting and/or investment power over the shares Heartland beneficially owns. The information set forth in this footnote is based on a Schedule 13G filed by Heartland on January 13, 2005.
- (13) Larry N. Feinberg and affiliates, Oracle Partners, L.P., Oracle Institutional Partners, L.P., Oracle Investment Management, Inc., and Sam Oracle Fund, Inc., 712 Fifth Avenue, 45th Floor, New York, NY 10019 are known to beneficially own more than ten percent of our common stock. The information set forth in this footnote is based on a Schedule 13D filed by Mr. Feinberg on November 14, 2002. Includes 730,000 shares of our common stock issuable upon conversion of Convertible Notes at a conversion price of \$5.50 per share. Mr. Duty, our director and partner in Oracle Partners, L.P., disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.
- (14) Does not include Heartland Advisors, Inc., Larry N. Feinberg and affiliates, or Kerry P. Gray.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On October 12, 2000, the Board authorized a restricted stock purchase program. Under the program, our executive officers were given the opportunity to purchase shares of common stock in an individually designated amount per participant determined by our Compensation Committee. A total of 180,000 shares were purchased by such officers at \$5.50 per share, the fair market value of the common stock on October 12, 2000, for an aggregate consideration of \$990,000. The purchase price was paid through the participant's delivery of a 50%-recourse promissory note payable to us. Each note bears interest at 5.87% compounded semi-annually and has a maximum term of ten years. The notes are secured by a pledge to us of the purchased shares. We recorded the notes receivable of \$990,000 from participants in this program as a reduction of equity in the Consolidated Balance Sheet. As of December 31, 2004, principal and interest on the notes was: Mr. Gray — \$702,000; Dr. Nowotnik — \$351,000; and Mr. Thompson — \$211,000. In accordance with the Sarbanes-Oxley Act of 2002, we no longer make loans to our executive officers.

Stephen B. Howell, MD. Dr. Howell, one of our directors, also serves as a scientific consultant pursuant to a consulting agreement with us that provides for a minimum of ten days consulting during 2005 at a rate of \$2,800 per month plus expenses. Dr. Howell received warrants to purchase 10,000 shares of our common stock at \$4.96 per share that can be exercised until January 1, 2009; warrants to purchase 15,000 shares of our common stock at \$3.00 per share that can be exercised until January 1, 2008; and, warrants to purchase 30,000 shares of our common stock at \$3.00 per share that were exercisable on or before February 1, 2005. During 2004, Dr. Howell was paid \$58,000 in consulting fees; during 2003 Dr. Howell was paid \$60,000 in consulting fees; and during 2002 Dr. Howell was paid \$55,000 in consulting fees. Dr. Howell's original agreement with us expired January 31, 2005 but was renewed and now expires February 28, 2006.

MARKET FOR OUR COMMON STOCK

Our common stock has traded on AMEX, since March 30, 2000 under the trading symbol AKC. The following table sets forth, for the periods indicated, the high and low closing prices for our common stock as reported by AMEX for the last two fiscal years are:

	Common Stock	
	High	Low
Fiscal 2005		
First quarter	\$ 3.48	\$ 2.42
Second quarter through May 26, 2005	2.88	1.92
Fiscal 2004		
First quarter	\$ 6.42	\$ 5.09
Second quarter	7.95	5.50
Third quarter	6.33	2.53
Fourth quarter	5.66	2.97
Fiscal 2003		
First quarter	\$ 2.74	\$ 1.75
Second quarter	3.50	1.81
Third quarter	4.40	2.91
Fourth quarter	5.50	3.75

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We have never declared or paid any cash dividends on our preferred stock or common stock and we do not anticipate paying any cash dividends in the foreseeable future. The payment of dividends, if any, in the future is within the discretion of our board of directors and will depend on our earnings, capital requirements and financial condition and other relevant facts. We currently intend to retain all future earnings, if any, to finance the development and growth of our business.

The number of record holders of our common stock at May 26, 2005 was approximately 5,900. On May 25, 2005, the closing price for our common stock as quoted on AMEX was \$2.35. There were 15,724,734 shares of common stock outstanding at May 9, 2005.

SELECTED CONDENSED CONSOLIDATED FINANCIAL INFORMATION

The following summary condensed consolidated financial information as of and for the years ended December 31, 2004, 2003, 2002, 2001 and 2000 have been derived from our audited financial statements. The financial information as of and for the three months ended March 31, 2005 and 2004 is derived from our unaudited consolidated financial statements. The summary condensed consolidated financial information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and notes thereto included elsewhere in this Prospectus.

	For the Three Months Ended March 31,		For the Year Ended December 31,				
	2005	2004	2004	2003	2002	2001	2000
(in thousands, except amounts per share)							
Consolidated Statement of Operations and Comprehensive Loss Data:							
Total revenues	\$ 155	\$ 20	\$ 549	\$ 1,295	\$ 1,147	\$ 243	\$ 107
Operating loss	(2,119)	(2,064)	(9,079)	(8,213)	(8,700)	(6,308)	(6,058)
Interest and miscellaneous income	10	33	226	2,559	594	1,451	972
Interest and other expense	(313)	(320)	1,385	1,281	1,278	1,170	342
Net loss	(2,422)	(2,351)	(10,238)	(6,935)	(9,384)	(6,027)	(5,428)
Common Stock Data:							
Net loss per basic and diluted common share	\$ (.16)	\$ (.17)	\$ (0.68)	\$ (0.52)	\$ (0.72)	\$ (0.47)	\$ (0.49)
Weighted average basic and diluted common shares outstanding	15,525	14,200	15,162	13,267	13,104	12,857	11,042

	For the Three Months Ended March 31,		For the Year Ended December 31,				
	2005	2004	2004	2003	2002	2001	2000
(in thousands, except amounts per share)							
Consolidated Balance Sheet Data:							
Cash, cash equivalents and short term investments	\$ 3,360	\$ 9,295	\$ 2,261	\$ 2,587	\$ 9,776	\$20,126	\$25,809
Restricted cash	398	619	1,284	649	468	600	—
Total assets	11,761	18,496	11,090	11,811	19,487	25,487	30,526
Deferred revenues	1,428	1,180	1,199	1,184	1,199	508	551
Convertible notes	16,163	13,530	13,530	13,530	13,530	13,530	13,530
Total liabilities	20,320	17,543	17,751	17,636	18,998	16,409	15,522
Total stockholders' equity (deficit)	(8,559)	953	(6,661)	(5,825)	489	9,078	15,004

SUPPLEMENTARY FINANCIAL INFORMATION

The information required by this item is set forth in Note 14, Quarterly Financial Data (unaudited) of the notes to our Consolidated Financial Statements appearing elsewhere in this Prospectus.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our excess cash and short-term investments in certificates of deposit, corporate securities with high quality ratings, and U.S. government securities. These investments are not held for trading or other speculative purposes. These financial investment securities all mature in 2005 and 2006 and their estimated fair value approximates cost. Changes in interest rates affect the investment income we earn on our investments and, therefore, impact our cash flows and results of operations. A hypothetical 50 basis point decrease in interest rates would result in a decrease in annual interest income and a corresponding increase in net loss of approximately \$3,000. This estimated effect assumes no changes in our short-term investments at March 31, 2005. We do not believe that we are exposed to any market risks, as defined. We are not exposed to risks for changes in commodity prices, or any other market risks.

DESCRIPTION OF SECURITIES

Our certificate of incorporation authorizes the issuance of 50,000,000 shares of our common stock, \$.01 par value per share, and 2,000,000 shares of preferred stock, \$.01 par value per share, which may be issued in one or more series. As of May 9, 2005 there were 15,724,734 shares of our common stock outstanding and held of record by approximately 5,900 stockholders, and there were no shares of our preferred stock outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and have the right to vote cumulatively for the election of directors. This means that in the voting at our annual meeting, each stockholder or his proxy, may multiply the number of his shares by the number of directors to be elected then cast the resulting total number of votes for a single nominee, or distribute such votes on the ballot among the nominees as desired. Holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our Board of Directors out of funds legally available therefor, subject to any preferential dividend rights for our outstanding preferred stock. Upon our liquidation, dissolution or winding up, the holders of our common stock are entitled to receive ratably our net assets available after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The outstanding shares of our common stock are, and the shares offered by the selling stockholders in this offering will be, fully paid and nonassessable. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock which we may designate and issue in the future.

Preferred Stock

Our Board of Directors is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 2,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control. The fact that our board of directors has the right to issue preferred stock without stockholder approval could be used to institute a "poison pill" that would work

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to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors. We have no present plans to issue any shares of preferred stock.

Transfer Agent and Registrar

The transfer agent and registrar of our common stock is American Stock Transfer & Trust Company, New York, New York.

Delaware Law and Certain Charter and By-Law Provisions

Certain anti-takeover provisions.

We are subject to the provisions of Section 203 of the General Corporation Law of Delaware. Section 203 prohibits certain publicly held Delaware corporations from engaging in a “business combination” with an “interested stockholder,” for a period of three years after the date of the transaction in which the person became an “interested stockholder,” unless the business combination is approved in a prescribed manner. A “business combination” includes mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an “interested stockholder” is a person or entity who, together with affiliates and associates, owns (or within the preceding three years, did own) 15% or more of the corporation’s voting stock. The statute contains provisions enabling a corporation to avoid the statute’s restrictions if the stockholders holding a majority of the corporation’s voting stock approve our Certificate of Incorporation provides that our directors shall be divided into three classes, with the terms of each class to expire on different years.

In addition, our Certificate of Incorporation, in order to combat “greenmail,” provides in general that any direct or indirect purchase by us of any of our voting stock or rights to acquire voting stock known to be beneficially owned by any person or group which holds more than five percent of a class of our voting stock and which has owned the securities being purchased for less than two years must be approved by the affirmative vote of at least two-thirds of the votes entitled to be cast by the holders of voting stock, subject to certain exceptions. The prohibition of “greenmail” may tend to discourage or foreclose certain acquisitions of our securities which might temporarily increase the price of our securities. Discouraging the acquisition of a large block of our securities by an outside party may also have a potential negative effect on takeovers. Parties seeking control of us through large acquisitions of its securities will not be able to resort to “greenmail” should their bid fail, thus making such a bid less attractive to persons seeking to initiate a takeover effort.

Elimination of Monetary Liability for Officers and Directors

Our Certificate of Incorporation incorporates certain provisions permitted under the General Corporation Law of Delaware relating to the liability of directors. The provisions eliminate a director’s liability for monetary damages for a breach of fiduciary duty, including gross negligence, except in circumstances involving certain wrongful acts, such as the breach of director’s duty of loyalty or acts or omissions, which involve intentional misconduct or a knowing violation of law. These provisions do not eliminate a director’s duty of care. Moreover, these provisions do not apply to claims against a Director for violations of certain laws, including certain federal securities laws. Our Certificate of Incorporation also contains provisions to indemnify the directors, officers, employees or other agents to the fullest extent permitted by the General Corporation Law of Delaware. We believe that these provisions will assist us in attracting and retaining qualified individual to serve as directors.

Indemnification of Officers and Directors

Our Certificate of Incorporation also contains provisions to indemnify the directors, officers, employees or other agents to the fullest extent permitted by the General Corporation Law of Delaware. These provisions may have the practical effect in certain cases of eliminating the ability of shareholders to collect monetary damages from directors. We believe that these provisions will assist us in attracting or retaining qualified individuals to serve as our directors.

EXPERTS

The financial statements as of December 31, 2004 included in this Prospectus and included elsewhere in the registration statement have been audited by Grant Thornton LLP, independent registered public accounting firm, as stated in their report appearing herein, and has been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

LEGAL MATTERS

Bingham McCutchen LLP will pass upon the validity of the shares of common stock offered hereby. Several partners of Bingham McCutchen LLP are also shareholders of Access.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission, Washington, D.C. 20549, under the Securities Act of 1933, a registration statement on Form S-1 relating to the shares of common stock offered hereby. This Prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to our company and the shares we are offering by this Prospectus you should refer to the registration statement, including the exhibits and schedules thereto. You may inspect a copy of the registration statement without charge at the Public Reference Section of the Securities and Exchange Commission at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission. The Securities and Exchange Commission also maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission. The Securities and Exchange Commission's World Wide Web address is <http://www.sec.gov>.

We file periodic reports, proxy statements and other information with the Securities and Exchange Commission in accordance with requirements of the Exchange Act. These periodic reports, proxy statements and other information are available for inspection and copying at the regional offices, public reference facilities and Internet site of the Securities and Exchange Commission referred to above. In addition, you may request a copy of any of our periodic reports filed with the Securities and Exchange Commission at no cost, by writing or telephoning us at the following address:

Investor Relations
Access Pharmaceuticals, Inc.
2600 Stemmons Freeway, Suite 176
Dallas, Texas 75207
(214) 905-5100

Information contained on our website is not a prospectus and does not constitute a part of this Prospectus.

You should rely only on the information contained in or incorporated by reference or provided in this Prospectus. We have not authorized anyone else 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 the information in this Prospectus is accurate as of any date other than the date on the front of this Prospectus.

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FINANCIAL STATEMENTS

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Report of Registered Independent Public Accounting Firm

Board of Directors and
Shareholders of Access Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Access Pharmaceuticals, Inc. (the “Company”), as of December 31, 2004 and 2003, and the related consolidated statements of operations and comprehensive loss, stockholders’ equity (deficit), and cash flows for each of the three years in the period ended December 31, 2004. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. Our audit included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Access Pharmaceuticals, Inc., as of December 31, 2004 and 2003, and the results of its consolidated operations and its consolidated cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company’s internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 31, 2005, expressed an adverse opinion both with respect to management’s assessment of internal control and the Company’s internal control over financial reporting as of December 31, 2004.

/s/ GRANT THORNTON LLP

Dallas, Texas
March 31, 2005

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and
Shareholders of Access Pharmaceuticals, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Controls Over Financial Reporting, that Access Pharmaceuticals, Inc. (the "Company"), maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment, and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. We have identified the following material weaknesses that have not been identified as material weaknesses in management's assessment. These material weaknesses did not result in any adjustments to the annual or interim consolidated financial statements, however; these material weaknesses could result in a material misstatement to future annual or interim consolidated financial statements that would not be prevented or detected.

1. The Company has a limited number of personnel with responsibility for accounting and financial reporting matters. As a result, there is a lack of segregation of duties over the initiation, authorization, recording and reporting of transactions and the preparation and review of financial statements by persons sufficiently independent of the transactions. These segregation of duties issues also extend to the Company's information technology controls whereby the personnel limitations result in individuals having the ability to initiate, approve and record transactions.

2. Our evaluation of the design of the Company's internal controls identified the following significant deficiencies that individually are not considered a material weakness; however, compensating or mitigating controls to prevent material misstatements occurring as a result of these deficiencies are dependent on adequate segregation of duties. Because of the inadequate segregation of duties present in the Company's control environment, these deficiencies represent, in the aggregate, a material weakness.

Lack of formal controls to monitor compliance with existing policies, practices and procedures, including within the information technology environment.

Reliance on undocumented controls to verify the accuracy of transactions and financial reporting.

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Consistency in the performance of manual controls and approvals at the transaction level and review of accounting and financial reporting information used to prepare financial statements.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2004 financial statements, and this report does not affect our report dated March 31, 2005, on those financial statements.

In our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, management's assessment that Access Pharmaceuticals, Inc., maintained effective internal control over financial reporting as of December 31, 2004, is not fairly stated, in all material respects, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Access Pharmaceuticals, Inc., has not maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Access Pharmaceuticals, Inc., as of December 31, 2004 and 2003, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2004, and our report dated March 31, 2005, expressed an unqualified opinion thereon.

/s/ GRANT THORNTON LLP

Dallas, Texas
March 31, 2005

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Access Pharmaceuticals, Inc. and Subsidiaries

CONSOLIDATED BALANCE SHEETS

	<u>December 31, 2004</u>	<u>December 31, 2003</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 1,775,000	\$ 727,000
Short term investments, at cost	486,000	1,860,000
Accounts and other receivables	791,000	1,149,000
Inventory	125,000	185,000
Prepaid expenses and other current assets	<u>1,093,000</u>	<u>898,000</u>
Total current assets	<u>4,270,000</u>	<u>4,819,000</u>
Property and equipment, net	1,040,000	1,004,000
Debt issuance costs, net	130,000	313,000
Patents, net	2,315,000	2,652,000
Licenses, net	125,000	367,000
Goodwill, net	1,868,000	1,868,000
Restricted cash and other assets	<u>1,342,000</u>	<u>788,000</u>
Total assets	<u>\$ 11,090,000</u>	<u>\$ 11,811,000</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable and accrued expenses	\$ 2,131,000	\$ 1,780,000
Accrued interest payable	311,000	311,000
Deferred revenues	1,199,000	1,184,000
Current portion of note payable and other future obligations	<u>8,417,000</u>	<u>338,000</u>
Total current liabilities	12,058,000	3,613,000
Long-term obligations for purchased patents	—	211,000
Note payable, net of current portion	193,000	282,000
Convertible notes	<u>5,500,000</u>	<u>13,530,000</u>
Total liabilities	<u>17,751,000</u>	<u>17,636,000</u>
Commitments and contingencies		
Stockholders' deficit		
Preferred stock — \$.01 par value; authorized 2,000,000 shares; none issued or outstanding	—	—
Common stock — \$.01 par value; authorized 50,000,000 shares; issued, 15,524,734 at December 31, 2004 and 13,397,034 at December 31, 2003	155,000	134,000
Additional paid-in capital	59,010,000	49,597,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Unamortized value of restricted stock grants	(309,000)	(294,000)
Treasury stock, at cost – 819 shares	(4,000)	(4,000)
Accumulated other comprehensive loss	(3,000)	14,000
Accumulated deficit	<u>(64,465,000)</u>	<u>(54,227,000)</u>
Total stockholders' deficit	<u>(6,661,000)</u>	<u>(5,825,000)</u>
Total liabilities and stockholders' deficit	<u>\$ 11,090,000</u>	<u>\$ 11,811,000</u>

The accompanying notes are an integral part of these statements.

Access Pharmaceuticals, Inc. and Subsidiaries

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year ended December 31,		
	2004	2003	2002
Revenues			
License revenues	\$ 104,000	\$ 729,000	\$ 853,000
Product sales	351,000	532,000	194,000
Research and development	—	—	89,000
Royalty income	94,000	34,000	11,000
Total revenues	549,000	1,295,000	1,147,000
Expenses			
Research and development	5,417,000	6,096,000	7,024,000
Cost of product sales	239,000	277,000	107,000
General and administrative	3,199,000	2,514,000	2,277,000
Depreciation and amortization	773,000	621,000	439,000
Total expenses	9,628,000	9,508,000	9,847,000
Loss from operations	(9,079,000)	(8,213,000)	(8,700,000)
Other income (expense)			
Interest and miscellaneous income	226,000	2,559,000	594,000
Interest and other expense	(1,385,000)	(1,281,000)	(1,278,000)
	(1,159,000)	1,278,000	(684,000)
Net loss	<u>\$(10,238,000)</u>	<u>\$(6,935,000)</u>	<u>\$(9,384,000)</u>
Basic and diluted loss per common share	<u>\$ (0.68)</u>	<u>\$ (0.52)</u>	<u>\$ (0.72)</u>
Weighted average basic and diluted common shares outstanding	<u>15,162,256</u>	<u>13,266,733</u>	<u>13,104,060</u>

The accompanying notes are an integral part of these statements.

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Access Pharmaceuticals, Inc. and Subsidiaries

CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock Shares	Common Stock Amount	Additional paid-in capital	Notes receivable from stockholders	Unamortized value of restricted stock grants	Treasury stock	Accumulated other comprehensive income (loss)	Accumulated deficit
Balance, January 1, 2002	12,909,000	\$132,000	\$48,057,000	\$(1,045,000)	\$ (154,000)	\$(4,000)	\$ —	\$(37,908,000)
Common stock for cash exercise of warrants and options	13,000	—	31,000	—	—	—	—	—
Common stock issued for cashless exercise of warrants	14,000	—	—	—	—	—	—	—
Common stock issued, purchase of assets	173,000	—	632,000	—	—	—	—	—
Warrants issued	—	—	80,000	—	—	—	—	—
Issuance of restricted stock grants	50,000	—	189,000	—	(190,000)	—	—	—
Other comprehensive loss	—	—	—	—	—	—	(14,000)	—
Amortization of restricted stock grants	—	—	—	—	67,000	—	—	—
Net loss	—	—	—	—	—	—	—	(9,384,000)
Balance, December 31, 2002	13,159,000	132,000	48,989,000	(1,045,000)	(277,000)	(4,000)	(14,000)	(47,292,000)
Common stock issued for cash exercise of warrants and options	103,000	1,000	266,000	—	—	—	—	—
Common stock issued for cashless exercise of warrants	80,000	1,000	(1,000)	—	—	—	—	—
Warrants issued	—	—	233,000	—	—	—	—	—
Issuance of restricted stock grants	55,000	—	110,000	—	(111,000)	—	—	—
Other comprehensive income	—	—	—	—	—	—	28,000	—
Amortization of restricted stock grants	—	—	—	—	94,000	—	—	—
Net loss	—	—	—	—	—	—	—	(6,935,000)
Balance, December 31, 2003	13,397,000	134,000	49,597,000	(1,045,000)	(294,000)	(4,000)	14,000	(54,227,000)
Common stock issued for cash, net of offering costs	1,789,000	18,000	8,998,000	—	—	—	—	—
Common stock issued for cash exercise of warrants and options	117,000	1,000	282,000	—	—	—	—	—
Common stock issued for cashless exercise of warrants	210,000	2,000	(2,000)	—	—	—	—	—
Issuance of restricted stock grants	12,000	—	135,000	—	(135,000)	—	—	—
Other comprehensive loss	—	—	—	—	—	—	(17,000)	—
Amortization of restricted stock grants	—	—	—	—	120,000	—	—	—
Net loss	—	—	—	—	—	—	—	(10,238,000)
Balance, December 31, 2004	<u>15,525,000</u>	<u>\$155,000</u>	<u>\$59,010,000</u>	<u>\$(1,045,000)</u>	<u>\$ (309,000)</u>	<u>\$(4,000)</u>	<u>\$ (3,000)</u>	<u>\$(64,465,000)</u>

The accompanying notes are an integral part of these statements.

Access Pharmaceuticals, Inc. and Subsidiaries
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2004	2003	2002
Cash flows from operating activities:			
Net loss	\$(10,238,000)	\$(6,935,000)	\$(9,384,000)
Adjustments to reconcile net loss to net cash used in operating activities:			
Warrants issued in payment of consulting expenses	—	57,000	34,000
Impairment of investment	112,000	—	—
Amortization of restricted stock grants	120,000	94,000	67,000
Depreciation and amortization	773,000	621,000	439,000
Amortization of debt costs	183,000	183,000	183,000
Other long-term obligations	—	—	43,000
Change in operating assets and liabilities:			
Accounts receivable	358,000	47,000	(1,080,000)
Inventory	60,000	353,000	(461,000)
Prepaid expenses and other current assets	(195,000)	130,000	(241,000)
Other assets	(666,000)	(209,000)	130,000
Accounts payable and accrued expenses	401,000	(689,000)	983,000
Accrued interest payable	—	—	1,000
Deferred revenue	15,000	(15,000)	691,000
Net cash used in operating activities	(9,077,000)	(6,363,000)	(8,595,000)
Cash flows from investing activities:			
Capital expenditures	(221,000)	(336,000)	(403,000)
Redemptions of short-term investments and certificates of deposit, net	1,374,000	6,472,000	4,368,000
Purchase of businesses, net of cash acquired	—	—	(1,313,000)
Net cash provided by investing activities	1,153,000	6,136,000	2,652,000
Cash flows from financing activities:			
Payments of notes payable	(310,000)	(784,000)	(107,000)
Proceeds from stock issuances, net	9,299,000	266,000	32,000
Net cash provided by (used in) financing activities	8,989,000	(518,000)	(75,000)
Net increase (decrease) in cash and cash equivalents	1,065,000	(745,000)	(6,018,000)
Effect of exchange rate changes on cash and cash equivalents	(17,000)	28,000	36,000
Cash and cash equivalents at beginning of year	727,000	1,444,000	7,426,000
Cash and cash equivalents at end of year	<u>\$ 1,775,000</u>	<u>\$ 727,000</u>	<u>\$ 1,444,000</u>
<i>Cash paid for interest</i>	<i>\$ 1,073,000</i>	<i>\$ 1,281,000</i>	<i>\$ 1,083,000</i>
<i>Cash paid for income taxes</i>	<i>—</i>	<i>—</i>	<i>—</i>
Supplemental disclosure of noncash transactions			
<i>Acquisitions of Australia patents</i>			
<i>Assets acquired</i>	<i>—</i>	<i>—</i>	<i>676,000</i>
<i>Stock and warrants issued</i>	<i>—</i>	<i>—</i>	<i>(676,000)</i>
<i>Value of restricted stock grants</i>	<i>135,000</i>	<i>111,000</i>	<i>190,000</i>
<i>Assets under capitalized lease capitalized during the year</i>	<i>59,000</i>	<i>126,000</i>	<i>—</i>

The accompanying notes are an integral part of these statements.

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Three years ended December 31, 2004

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Nature of Operations

Access Pharmaceuticals, Inc. is a diversified emerging pharmaceutical company engaged in the development of novel therapeutics based primarily on the adaptation of existing therapeutic agents using its proprietary drug delivery platforms. Our efforts have been principally devoted to research and development, resulting in significant losses since inception on February 24, 1988. Prior to 2002, we presented our financial statements as a development stage enterprise.

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

Principles of Consolidation

The consolidated financial statements include the financial statements of Access Pharmaceuticals, Inc. and our wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents

We consider all highly liquid instruments with an original maturity of three months or less to be cash equivalents for purposes of the statements of cash flows. We invest our excess cash in government and corporate securities. Cash and cash equivalents consist primarily of cash in banks, money market funds and short-term corporate securities. All other investments are reported as short-term investments.

Short-term Investments

Short-term investments consist of certificates of deposit. All short term investments are classified as held to maturity. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included in interest income. The cost of securities sold is based on the specific identification method.

Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over estimated useful lives ranging from three to seven years.

Patents and Applications

We expense internal patent and application costs as incurred because, even though we believe the patents and underlying processes have continuing value, the amount of future benefits to be derived therefrom are uncertain. Purchased patents are capitalized and amortized over the life of the patent.

Licenses

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

Allowance for Doubtful Accounts

The Company estimates the collectibility of its trade accounts receivable. In order to assess the collectibility of these receivables, the Company monitors the current creditworthiness of each customer and analyzes the balances aged beyond the customer's credit terms. These evaluations may indicate a situation in which a certain customer cannot meet its financial obligations due to deterioration of its financial viability, credit ratings or bankruptcy. The allowance requirements are based on

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

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

current facts and are reevaluated and adjusted as additional information is received. Trade accounts receivable are reserved when it is probable that the balance will not be collected.

Revenue Recognition

Licensing revenues are recognized over the period of our performance obligation. Licensing agreements generally require payments of fees on executing the agreement with milestone payments based on regulatory approvals and cumulative sales. Some agreements allow for the return of a portion of the initial execution fee if regulatory approvals are not received. In these cases the refundable balance is included as deferred revenue. Many of our agreements are for ten years with automatic extensions. Sponsored research and development revenues are recognized as research and development activities are performed under the terms of research contracts. Advance payments received are recorded as deferred revenue until the related research activities are performed. Royalty income is recognized as earned at the time the licensed product is sold. Option revenues are recognized when the earnings process is completed pursuant to the terms of the respective contract.

Revenue from product sales is recognized when the customer's order is shipped from our third party logistics company's warehouse.

Research and Development Expenses

Pursuant to SFAS No. 2, "*Accounting for Research and Development Costs*," our research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, preclinical, development cost, clinical trial expense, outside manufacturing and consulting. The cost of materials and equipment or facilities that are acquired for research and development activities and that have alternative future uses are capitalized when acquired.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A valuation allowance is provided for deferred tax assets to the extent their realization is in doubt.

Loss Per Share

We have presented basic loss per share, computed on the basis of the weighted average number of common shares outstanding during the year, and diluted loss per share, computed on the basis of the weighted average number of common shares and all dilutive potential common shares outstanding during the year. Potential common shares result from stock options, convertible notes and warrants. However, for all years presented, all outstanding stock options, convertible notes and warrants are anti-dilutive.

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

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

Investment Securities

Investment securities consist of available for sale equity securities and short term investment are accounted for by the cost method. Available for sale securities are carried at fair value based on quoted market prices. Unrealized holding gains and losses, net of the related tax effect, on available for sale securities are excluded from earnings and are reported as a separate component of stockholders' equity until realized. Decline in the fair value of any available for sale security below cost that is determined to be other than temporary is charged to the statement of income. Realized gains and losses from the sale of available for sale securities are determined on average cost method and are included in earnings. Short-term investments consist of certificate of deposits, are held to maturity and are stated at cost.

Exchange Rate Translation

For international operations, local currencies have been determined to be the functional currencies. We translate assets and liabilities to their U.S. dollar equivalents at rates in effect at the balance sheet date and record translation adjustments in *Shareholders' equity*. We translate statement of income accounts at average rates for the period. Transaction adjustments are recorded in *Other (income)/expense*.

Restricted Cash

Restricted cash is cash that is or may be committed for a particular purpose. We have restricted cash for a deferred license agreement (\$839,000), for a note payable (\$233,000), and for rent guarantees for a manufacturing agreement and laboratory (\$213,000).

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – Continued

Acquisition-Related Intangible Assets and Change In Accounting Principles

Effective January 1, 2002, we adopted SFAS 142, “*Goodwill and Other Intangible Assets*.” Under SFAS 142, goodwill is no longer amortized but is subject to an impairment test at least annually or more frequently if impairment indicators arise. Separately identified and recognized intangible assets resulting from business combinations completed before July 1, 2001 that did not meet the new criteria for separate recognition of intangible assets were subsumed in goodwill upon adoption. The intangible assets of the company that did not meet the separate recognition criteria were licenses and acquired patents. We continue to amortize intangible assets that meet the new criteria over their useful lives. In accordance with SFAS 142, we performed a transitional impairment test of goodwill as of January 1, 2002, and an annual test in the fourth quarter of 2004, 2003 and 2002, which did not result in an impairment of goodwill.

Intangible assets consist of the following (in thousands):

	December 31, 2004		December 31, 2003		December 31, 2002	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
Amortizable intangible assets						
Patents	\$ 3,179	\$ 864	\$ 3,179	\$ 527	\$ 3,179	\$ 188
Licenses	500	375	830	463	830	381
Total	<u>\$ 3,679</u>	<u>\$ 1,239</u>	<u>\$ 4,009</u>	<u>\$ 990</u>	<u>\$ 4,009</u>	<u>\$ 569</u>
Intangible assets not subject to amortization						
Goodwill	<u>\$ 2,464</u>	<u>\$ 596</u>	<u>\$ 2,464</u>	<u>\$ 596</u>	<u>\$ 2,464</u>	<u>\$ 596</u>

The Company determined that one of its licenses was no longer useful for its current business focus and expensed \$109,000 for the license net of amortization and royalty payable.

Amortization expense related to intangible assets totaled \$420,000, \$421,000 and \$301,000 for the year ended December 31, 2004, 2003 and 2002, respectively. The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2004 is as follows (in thousands):

2005	\$ 388
2006	388
2007	363
2008	338
	338
Thereafter	<u>625</u>
Total	<u>\$ 2,440</u>

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – Continued

Stock-Based Compensation

We account for our stock option plan in accordance with the provisions of Accounting Principles Board (“APB”) Opinion No. 25, Accounting for Stock Issued to Employees, and related interpretations. Compensation expense is recorded only if the current market price of the underlying stock exceeds the exercise price on the date of grant. We have adopted the disclosure provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation, which recognizes the fair value of all stock-based awards on the date of grant.

At December 31, 2004 we had two stock-based employee compensation plans, which are described more fully in Note 11. No stock-based employee compensation cost, other than compensation associated with options assumed in acquisitions, is reflected in net loss, as all options granted under those plans had an exercise price equal to the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net loss and net loss per share if we had applied the fair value recognition provisions of SFAS 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	December 31,		
	2004	2003	2002
Net loss			
As reported	\$(10,238,000)	\$(6,935,000)	\$ (9,384,000)
Pro forma stock option expense	(738,000)	(1,232,000)	(1,662,000)
Pro forma	<u>(10,976,000)</u>	<u>(8,167,000)</u>	<u>(11,046,000)</u>
Basic and diluted loss per share			
As reported	(\$.68)	(\$.52)	(\$.72)
Pro forma stock option expense	(.05)	(.09)	(.12)
Pro forma	<u>(\$.73)</u>	<u>(\$.61)</u>	<u>(\$.84)</u>

The effect of our outstanding options and warrants are anti-dilutive when we have a net loss. The fully diluted shares are:

	December 31,		
	2004	2003	2002
Fully diluted shares	20,567,301	18,837,344	18,786,202

Stock compensation expense for options granted to nonemployees has been determined in accordance with SFAS 123 and EITF 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured.

Recent Accounting Pronouncement

On December 16, 2004, the FASB issued FAS 123R, *Share-Based Payment — An Amendment of FASB Statements No. 123 and 95*, (FAS 123R) which is effective for public companies in periods beginning after June 15, 2005. We will be required to implement the proposed standard no later than the quarter that begins July 1, 2005. The cumulative effect of adoption, if any, applied on a modified prospective basis, would be measured and recognized on July 1, 2005. FAS 123R addresses the accounting for transactions in which an enterprise receives employee services in exchange for (a) equity instruments of the enterprise or (b) liabilities that are based on the fair value of the enterprise’s equity instruments or that may be settled by the issuance of such equity instruments. FAS 123R would eliminate the ability to account for share-based compensation transactions using APB 25, and generally would require instead that such transactions be accounted for using a fair-value based method. Companies will be required to recognize an expense for compensation cost related to share-based payment arrangements including stock options and employee stock purchase plans.

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – Continued

We are currently evaluating option valuation methodologies and assumptions of FAS 123R related to share based payments and the effect of adopting this pronouncement.

Use of Estimates

In preparing consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

We tested goodwill for impairment based on estimates of fair value. It is at least reasonably possible that the estimates used by us will be materially different from actual amounts. These differences could result in the impairment of all or a portion of our goodwill, which could have a materially adverse effect on our results of operations.

Fair Value of Financial Instruments

The carrying value of cash, cash equivalents, short-term investments and certificates of deposit approximates fair value due to the short maturity of these items. It is not practical to estimate the fair value of the Company's long-term debt because quoted market prices do not exist and there were no available securities to use as a basis to value our debt.

NOTE 2 – LIQUIDITY

The Company incurred significant losses from operations of \$9.1 million for the year ended December 31, 2004 and \$8.2 million for the year ended December 31, 2003. Additionally, at December 31, 2004, we have a working capital deficit of \$7,788,000. As of December 31, 2004, we did not have sufficient funds to repay our convertible notes at their maturity and support our working capital and operating requirements. As described below, in March 2005, we entered into financing arrangements we believe will allow us to meet our obligations under the convertible notes in the event we are unable to restructure or cause on terms acceptable to us.

As of March 30, 2005, the Company executed the Standby Equity Distribution Agreement with Cornell Capital Partners. Under the Standby Equity Distribution Agreement, the Company may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to \$15,000,000. The purchase price for the shares is equal to their market price, which is defined in the Standby Equity Distribution Agreement as 98% the lowest VWAP of our common stock during the five consecutive trading day period immediately following the date we notify Cornell Capital Partners that we desire to access the Standby Equity Distribution Agreement. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the Equity Line of Credit. The amount of each draw down is subject to a maximum amount of \$1,000,000. The terms of the Standby Equity Distribution Agreement do not allow us to make any draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our outstanding shares of common stock. Based on the number of shares of our common stock currently outstanding, at volume weighted average price of \$2.50, we could sell to Cornell Capital approximately \$3,900,000 of our common stock subject to the 9.9% limitation. Thus, in order for the Company to receive all the funding available under the Standby Equity Distribution Agreement and have the financial resources it needs for operations and debt service, Cornell Capital must sell through to the market a significant portion of the shares it purchases under the arrangement. The Company believes that because the shares sold to Cornell Capital will be covered by an effective registration statement and Cornell Capital has a history of not holding significant positions in companies in which it invests, the shares purchased by Cornell Capital will be sold to the marketplace to maintain ownership below 9.9%. Provided that continuing sales to the marketplace are possible, the Company believes Cornell Capital will not accumulate 9.9% of the outstanding common stock of the Company; and, accordingly, the Company will be able to fully utilize the \$15,000,000 made available through the Standby Equity Distribution Agreement.

Upon closing of the transaction, Cornell Capital Partners will receive a one-time commitment fee of 146,500 shares of the Company's common stock. On the same date, the Company entered into a placement agent agreement in

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

NOTE 2 – LIQUIDITY – CONTINUED

escrow with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the placement agent agreement, upon closing of the transaction the Company will pay a one-time placement agent fee of 3,500 shares of common stock.

In addition, as of March 30, 2005, the Company executed a securities purchase agreement with Cornell Capital Partners and Highgate House Funds. Under the securities purchase agreement, upon closing Cornell Capital Partners and Highgate House Funds are obligated to purchase an aggregate of \$2,633,000 principal amount of secured convertible debentures from the Company (net proceeds to the Company of \$2,360,000). The secured convertible debentures accrue interest at a rate of 7% per year and mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the secured convertible debenture has not been converted to common stock. The secured convertible debenture is convertible into the Company's common stock at the holder's option any time up to maturity at a conversion price equal to \$4.00. The secured convertible debentures are secured by all of the assets of the Company. The Company has the right to redeem the secured convertible debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the securities purchase agreement, the Company is required to issue to the holders an aggregate of 50,000 shares of common stock of the Company.

The Company believes that based on the funds available from the agreements referred to above, as well as revenues from our operations, the Company will have the ability to pay its debt and other obligations as they come due.

NOTE 3 — ACQUISITIONS

Our wholly-owned subsidiary, Access Pharmaceuticals Australia Pty. Limited acquired the targeted therapeutic technology business of Biotech Australia Pty. Ltd under an Asset Sale Agreement dated February 26, 2002. Under the terms of the Asset Sale Agreement, Access Pharmaceuticals Australia Pty. Limited acquired the patents to three targeted therapeutics technologies and retained the scientific group that has developed this technology. The total consideration payable by us will be paid in a combination of cash and stock over a three-year period and is dependent on the achievement of certain technology milestones. We paid \$500,000 at closing and an additional total of up to \$525,000 will be paid over a three-year period. We also issued as consideration 172,584 shares of our common stock (valued at \$633,000) and warrants to purchase 25,000 shares of our common stock at an exercise price of \$5.00 per share (valued at \$43,000 using the Black-Scholes option pricing model). The liability of \$175,000 at December 31, 2004 was paid in 2005.

The three patented targeted therapeutic technologies acquired in this transaction are:

- o folate conjugates of polymer therapeutics to enhance tumor delivery by targeting folate receptors which are upregulated in certain tumor types;
- o the use of vitamin B12 to target the transcobalamin II receptor which is upregulated in numerous diseases including cancer, rheumatoid arthritis and certain neurological and autoimmune disorders; and
- o oral delivery of a wide variety of molecules, which cannot otherwise be orally administered, using the active transport mechanism which transports vitamin B12 into the systemic circulation.

The cost of the acquisition has been assigned principally to patents and will be amortized over the remaining useful life of the patents which averages ten years.

On July 22, 2002, we acquired from GlaxoSmithKline the patents, trademarks and technology covering the use of amlexanox for the treatment of mucosal and skin disorders. The two major components of the acquisition are the US marketing rights to amlexanox 5% paste which is currently marketed for the treatment of canker sores under the trademark Aphthasol®, and the remaining worldwide marketing rights for this indication which were the subject of a prior licensing agreement between the companies. Under the terms of the agreement, we made an initial upfront payment of \$750,000 and an additional payment of \$250,000 on January 22, 2003.

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

NOTE 4 — RELATED PARTY TRANSACTIONS

Under a former consulting agreement between Thoma Corporation (“Thoma”) and us, Thoma received payments for consulting services and reimbursement of direct expenses. Herbert H. McDade, Jr., our past Chairman of the Board of Directors, is an owner of Thoma Corp. Thoma received payments for consulting services and was also reimbursed for expenses as follows:

Year	Consulting Fees	Expense Reimbursement
2002	\$ 18,000	\$ —

Stephen B. Howell, M.D., a Director, receives payments for consulting services and reimbursement of direct expenses and has also received warrants for his consulting services. Dr. Howell’s payments for consulting services, expense reimbursements and warrants are as follows:

Year	Consulting Fees	Expense Reimbursement	Warrants	Exercise Price	Fair Value
2004	\$ 58,000	\$ 9,000	—	\$ —	\$ —
2003	\$ 60,000	\$ 6,000	30,000	\$ 3.00	\$30,000
2002	\$ 55,000	\$ 3,000	10,000	\$ 4.91	\$37,000

See Note 10 for a discussion of our Restricted Stock Purchase Program.

NOTE 5 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	December 31,	
	2004	2001
Laboratory equipment	\$2,208,000	\$1,972,000
Laboratory and building improvements	167,000	166,000
Furniture and equipment	204,000	196,000
	<u>2,579,000</u>	<u>2,334,000</u>
Less accumulated depreciation and amortization	<u>1,539,000</u>	<u>1,330,000</u>
Net property and equipment	<u>\$1,040,000</u>	<u>\$1,004,000</u>

Depreciation and amortization on property and equipment was \$244,000, \$200,000, and \$138,000 for the years ended December 31, 2004, 2003 and 2002, respectively.

NOTE 6 – 401(k) PLAN

We have a tax-qualified employee savings and retirement plan (the “401(k) Plan”) covering all our employees. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit (\$13,000 in 2004; \$12,000 in 2003; and \$11,000 in 2002) and to have the amount of such reduction contributed to the 401(k) Plan. We have a 401(k) matching program whereby we contribute for each dollar a participant contributes a like amount, with a maximum contribution of 2% of a participant’s earnings. The 401(k) Plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees or by us to the 401(k) Plan, and income earned on 401(k) Plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made. At the direction of each participant, we invest the assets of the 401(k) Plan in any of 23 investment options. Company contributions under the 401(k) Plan were approximately \$46,000 in 2004; \$45,000 in 2003; and \$37,000 in 2002.

Access Pharmaceuticals, Inc. and SubsidiariesNOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004**NOTE 7 – NOTE PAYABLE AND OTHER OBLIGATIONS**

On September 20, 2001, we completed a \$600,000 installment loan with a bank. The balance at December 31, 2004 is \$233,000. The loan was used to purchase capital equipment and for leasehold improvements to expand our laboratory and office space. The loan is due in 60 equal installments, including interest at 6.5%. The loan is secured by a \$233,000 certificate of deposit classified as an other asset at December 31, 2004.

On February 26, 2002, our wholly-owned subsidiary, Access Pharmaceuticals Australia Pty. Limited acquired the targeted therapeutic technology business of Biotech Australia Pty. Ltd under an Asset Sale Agreement. The last \$175,000 payment was due and paid in the first quarter of 2005.

Future maturities of the note payable and other obligations are as follows:

Future Maturities	Notes payable and other obligations	Capital leases	Total
2005	\$ 305,000	\$ 82,000	\$387,000
2006	103,000	36,000	139,000
Thereafter	53,000	—	54,000
	\$ 461,000	\$118,000	\$580,000

NOTE 8 – CONVERTIBLE NOTES

On September 20, 2000, we completed a \$13.5 million convertible note offering. The offering was placed with three investors. Our convertible notes are due in two parts, \$8,030,000 due on September 13, 2005 and \$5,500,000 due on September 13, 2007. The notes bear interest at 7.7% per annum with \$1,041,000 of interest due annually on September 13th. The notes have a fixed conversion price of \$5.50 per share of common stock and may be converted by the note holder or us under certain circumstances as defined in the note. If the notes are not converted we will have to repay the notes on the due dates. Total expenses of issuance were \$915,000 and are amortized over the life of the notes.

NOTE 9 — COMMITMENTS

At December 31, 2004, we have commitments under noncancelable operating leases for office and research and development facilities and equipment as follows:

	Operating leases
2005	\$305,000
2006	181,000
2007	140,000
2008	47,000
Total future minimum lease payments	\$673,000

Rent expense for the years ended December 31, 2004, 2003 and 2002 was \$166,000, \$165,000 and \$138,000, respectively.

Access Pharmaceuticals, Inc. and SubsidiariesNOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004**NOTE 10 — STOCKHOLDERS' EQUITY**Restricted Stock Purchase Program

On October 12, 2000, the Board of Directors authorized a Restricted Stock Purchase Program. Under the Program, the Company's executive officers and corporate secretary were given the opportunity to purchase shares of common stock in an individually designated amount per participant determined by the Compensation Committee of the Board of Directors. A total of 190,000 shares were purchased under the Program by four eligible participants at \$5.50 per share, the fair market value of our common stock on October 12, 2000, for an aggregate consideration of \$1,045,000. The purchase price was paid through the participant's delivery of a 50%-recourse promissory note payable to the Company for three executive officer participants and a full-recourse promissory note payable to the Company for the corporate secretary. Each note bears interest at 5.87% compounded semi-annually and has a maximum term of ten years. The notes are secured by a pledge of the purchased shares to the Company. The Company recorded the notes receivable from participants in this Program of \$1,045,000 as a reduction of equity in the Consolidated Balance Sheet. Interest on the notes is neither being collected nor accrued.

The stock granted under the Program other than to the corporate secretary vested ratably over a four year period and is now fully vested. The stock granted to the corporate secretary vested on the date of grant.

Warrants

There were warrants to purchase a total of 770,420 shares of common stock outstanding at December 31, 2004. All warrants were vested and exercisable at December 31, 2004. The warrants had various prices and terms as follows:

<u>Summary of Warrants</u>	<u>Warrants Outstanding</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
2004 offering (a)	447,344	\$ 7.10	2/24/09
2004 offering (a)	156,481	5.40	2/24/09
2003 financial advisor (b)	72,000	3.90	10/30/08
2003 scientific consultant (c)	30,000	3.00	1/1/06
2002 warrants offered in acquisition (d)	25,000	5.00	2/26/05
2002 scientific consultant (e)	10,000	4.96	2/01/09
2001 scientific consultant (f)	15,000	3.00	1/1/08
2000 offering (g)	14,595	2.50	3/01/05
Total	770,420		

- (a) In connection with offering of common stock in 2004, warrants to purchase a total of 603,825 shares of common stock were issued. All of the warrants are exercisable immediately and expire five years from date of issuance.
- (b) During 2003, financial advisors received warrants to purchase 72,000 shares of common stock at any time from October 30, 2003 until October 30, 2008, for financial consulting services rendered in 2003 and 2004. All the warrants are exercisable. The fair value of the warrants was \$2.82 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.9%, expected volatility 92% and a term of 5 years.

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

NOTE 10 — STOCKHOLDERS' EQUITY — Continued

- (c) During 2003, a director who is also a scientific advisor received warrants to purchase 30,000 shares of common stock at an exercise price of \$3.00 per share at any time from January 1, 2003 until January 1, 2006, for scientific consulting services rendered in 2003. The fair value of the warrants was \$.99 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.26%, expected volatility 98% and a term of 3 years.
- (d) During 2002, a company received warrants to purchase 25,000 shares of common stock at an exercise price of \$5.00 per share at any time from February 26, 2002 until February 26, 2005. The warrants were issued in connection with the acquisition of patents in Australia. The fair value of the warrants was \$1.72 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.67%, expected volatility 81% and a term of 3 years. The warrants expired on February 26, 2005 without being exercised.
- (e) During 2002, a director who is also a scientific advisor received warrants to purchase 10,000 shares of common stock at an exercise price of \$4.91 per share at any time from February 1, 2002 until February 1, 2009, for scientific consulting services rendered in 2002. The fair value of the warrants was \$3.70 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.90%, expected volatility 81% and a term of 7 years.
- (f) During 2001, a director who is also a scientific advisor received warrants to purchase 15,000 shares of common stock at an exercise price of \$3.00 per share at any time from January 1, 2001 until January 1, 2008, for scientific consulting services rendered in 2001. The fair value of the warrants was \$2.74 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 5.03%, expected volatility 118% and a term of 7 years.
- (g) In connection with offerings of common stock in 2000, warrants to purchase a total of 509,097 shares of common stock were issued. All of the warrants are exercisable immediately and expire five years from date of issuance.

2001 Restricted Stock Plan

We have a restricted stock plan, the 2001 Restricted Stock Plan, under which 200,000 shares of our authorized but unissued common stock were reserved for issuance to certain employees, directors, consultants and advisors. The restricted stock granted under the plan generally vests over five years, 25% two years after the grant date with additional 25% vesting every anniversary date. All stock is vested after five years. At December 31, 2004 there were 161,238 shares granted and 38,762 shares available for grant under the 2001 Restricted Stock Plan.

Access Pharmaceuticals, Inc. and SubsidiariesNOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004**NOTE 11 — STOCK OPTION PLANS**

We have a stock option plan, as amended, (the “1995 Stock Awards Plan”), under which 2,500,000 shares of our authorized but unissued common stock were reserved for issuance to optionees including officers, employees, and other individuals performing services for us. The 1995 Stock Awards Plan replaced the previously approved stock option plan (the “1987 Stock Awards Plan”). On February 11, 2000, we adopted the 2000 Special Stock Option Plan and Agreement (the “Plan”). The Plan provides for the award of options to purchase 500,000 shares of the authorized but unissued shares of common stock of the Company. Options granted under all the plans generally vest ratably over a four to five year period and are generally exercisable over a ten-year period from the date of grant. Stock options are generally granted with an exercise price equal to the market value at the date of grant.

At December 31, 2004, there were 129,780 additional shares available for grant under the 1995 Stock Awards Plan.

The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in fiscal 2004, 2003 and 2002, respectively: dividend yield of 0% for all periods; volatility of 41%, 117% and 98%; risk-free interest rates of 3.61%, 2.26% and 2.03%, respectively, and expected lives of four years for all periods. The weighted average fair values of options granted were \$2.18, \$1.56 and \$2.46 per share during 2004, 2003 and 2002, respectively.

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

	Shares	Weighted- average exercise price
Outstanding options at January 1, 2002	1,280,584	\$ 3.68
Granted, fair value of \$2.46 per share	493,000	3.53
Exercised	(2,428)	2.08
Forfeited	(60,000)	3.17
Outstanding options at December 31, 2002	1,711,156	3.59
Granted, fair value of \$1.56 per share	374,500	2.20
Exercised	(28,000)	2.55
Forfeited	(4,000)	2.70
Outstanding options at December 31, 2003	2,053,656	3.45
Granted, fair value of \$2.18 per share	314,200	5.75
Exercised	(109,695)	2.38
Forfeited	(75,980)	4.21
Outstanding options at December 31, 2004	2,182,181	3.76
Exercisable at December 31, 2002	997,570	3.35
Exercisable at December 31, 2003	1,389,185	3.49
Exercisable at December 31, 2004	1,671,160	3.64

Access Pharmaceuticals, Inc. and SubsidiariesNOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004**NOTE 11 — STOCK OPTION PLANS — Continued**

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2004 is summarized below:

Range of exercise prices	Number of shares outstanding	Weighted average		Number of shares exercisable	Weighted-average exercise price
		Remaining life in years	Exercise price		
\$2.00-2.18	417,063	6.5	\$ 2.01	333,436	\$ 2.01
\$2.30-2.81	352,100	7.8	2.44	275,183	2.47
\$2.94-3.99	716,318	6.4	3.43	585,104	3.36
\$4.05-7.8125	696,700	7.7	5.82	477,437	5.80
	<u>2,182,181</u>			<u>1,671,160</u>	

Under the 2000 Special Stock Option Plan, 500,000 options were issued in 2000 and are outstanding at December 31, 2004. All of the options in the 2000 Special Stock Option Plan were exercisable at December 31, 2004, 468,749 of the options were exercisable at December 31, 2003 and 343,749 of the options were exercisable at December 31, 2002. All of the options expire on March 1, 2010 and have an exercise price of \$2.50 per share.

All issued options under the 1987 Stock Awards Plan expired in 2004. No further grants can be made. Summarized information for the 1987 Stock Awards Plan is as follows:

	Stock options	Weighted- average exercise price
Outstanding awards at January 1, 2002	26,002	\$ 46.18
Forfeited	<u>(8,824)</u>	90.45
Outstanding awards at December 31, 2002	17,178	23.31
Forfeited	<u>(5,750)</u>	35.00
Outstanding awards at December 31, 2003	11,428	17.42
Forfeited	<u>(11,428)</u>	17.42
Outstanding awards at December 31, 2004	<u>—</u>	

Access Pharmaceuticals, Inc. and Subsidiaries

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004

NOTE 12 — INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

	2004	2003	2002
Income taxes at U.S. statutory rate	\$(3,442,000)	\$(2,358,000)	\$(3,191,000)
Change in valuation allowance	1,493,000	(111,000)	1,153,000
Expenses not deductible	7,000	40,000	15,000
Expiration of net operating loss and general business credit carryforwards, net of revisions	1,942,000	2,429,000	2,023,000
Total tax expenses:	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

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

	December 31,		
	2004	2003	2002
Deferred tax assets (liabilities)			
Net operating loss carryforwards	\$ 20,808,000	\$ 20,193,000	\$ 20,487,000
General business credit carryforwards	2,094,000	1,960,000	1,356,000
Property, equipment and goodwill	259,000	113,000	119,000
Gross deferred tax assets	23,161,000	22,266,000	21,962,000
Valuation allowance	(23,161,000)	(22,266,000)	(21,962,000)
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2004, we had approximately \$55,488,000 of net operating loss carryforwards and approximately \$2,094,000 of general business credit carryforwards. These carryforwards expire as follows:

	Net operating loss carryforwards	General business credit carryforwards
2005	\$ 3,014,000	\$ 26,000
2006	587,000	38,000
2007	994,000	26,000
2008	4,004,000	138,000
2009	1,661,000	185,000
Thereafter	45,228,000	1,681,000
	<u>\$ 55,488,000</u>	<u>\$ 2,094,000</u>

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

Access Pharmaceuticals, Inc. and SubsidiariesNOTES TO CONSOLIDATED FINANCIAL STATEMENTS — CONTINUED
Three years ended December 31, 2004**NOTE 13 — SETTLEMENT WITH BLOCK DRUG COMPANY**

On July 22, 2002, we entered into a Supply Agreement whereby Block Drug Company (Block) was required to produce Aphthasol® for us for a defined period of time at its Puerto Rico facility. Subsequently we were advised by Block that it was unable to produce Aphthasol® for us pursuant to the Supply Agreement. In May 2003, we reached a settlement with Block relating to this matter whereby Block made a one-time cash payment to us, we recorded \$2,280,000 in Miscellaneous Income and Block was relieved of its obligations under the Supply Agreement and the Asset Sale Agreement, pursuant to which we had purchased certain assets relating to amlexanox and Aphthasol® from Block, and we were relieved from certain future obligations under the Asset Sale Agreement.

NOTE 14 — QUARTERLY FINANCIAL DATA (UNAUDITED)

Our results of operations by quarter for the years ended December 31, 2004 and 2003 were as follows (in thousands, except per share amounts):

	2004 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue	\$ 20	\$ 68	\$ 185	\$ 276
Operating loss	(2,064)	(2,176)	(2,229)	(2,610)
Net loss	<u>\$ (2,351)</u>	<u>\$ (2,553)</u>	<u>\$ (2,428)</u>	<u>\$ (2,906)</u>
Basic and diluted loss per common share	<u>\$ (0.17)</u>	<u>\$ (0.17)</u>	<u>\$ (0.16)</u>	<u>\$ (0.18)</u>

	2003 Quarter Ended			
	March 31	June 30	September 30	December 31
Revenue	\$ 393	\$ 683	\$ 11	\$ 208
Operating loss	(2,194)	(1,694)	(1,943)	(2,382)
Net income (loss)	<u>\$ (2,411)</u>	<u>\$ 316</u>	<u>\$ (2,206)</u>	<u>\$ (2,634)</u>
Basic and diluted income (loss) per common share	<u>\$ (0.18)</u>	<u>\$ 0.02</u>	<u>\$ (0.17)</u>	<u>\$ (0.19)</u>

Access Pharmaceuticals, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	<u>March 31, 2005</u> (unaudited)
ASSETS	
Current assets	
Cash and cash equivalents	\$ 2,888,000
Short term investments, at cost	472,000
Accounts and other receivables	764,000
Inventory	113,000
Prepaid expenses and other current assets	957,000
Total current assets	<u>5,194,000</u>
Property and equipment, net	982,000
Debt issuance costs, net	917,000
Patents, net	2,231,000
Licenses, net	113,000
Goodwill, net	1,868,000
Restricted cash and other assets	<u>456,000</u>
Total assets	<u>\$ 11,761,000</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT	
Current liabilities	
Accounts payable and accrued expenses	\$ 1,800,000
Accrued interest payable	572,000
Deferred revenues	1,428,000
Current portion of notes payable and other future obligations	10,868,000
Total current liabilities	14,668,000
Note payable, net of current portion	152,000
Convertible note	<u>5,500,000</u>
Total liabilities	<u>20,320,000</u>
Commitments and contingencies	
Stockholders' deficit	
Preferred stock — \$.01 par value; authorized 2,000,000 shares; none issued or outstanding	
Common stock — \$.01 par value; authorized 50,000,000 shares; issued, 15,724,734 at March 31, 2005	157,000
Additional paid-in capital	59,508,000
Notes receivable from stockholders	(1,045,000)
Unamortized value of restricted stock grants	(277,000)
Treasury stock, at cost - 819 shares	(4,000)
Accumulated other comprehensive loss	(11,000)
Accumulated deficit	<u>(66,887,000)</u>
Total stockholders' deficit	<u>(8,559,000)</u>
Total liabilities and stockholders' deficit	<u>\$ 11,761,000</u>

The accompanying notes are an integral part of these statements.

[Table of Contents](#)**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Operations and Comprehensive Loss

(unaudited)

	Three Months ended March 31,	
	2005	2004
Revenues		
Licensing revenues	\$ 11,000	\$ 4,000
Product sales	117,000	—
Royalty income	<u>27,000</u>	<u>16,000</u>
Total revenues	155,000	20,000
Expenses		
Research and development	1,319,000	1,144,000
Costs of product sales	102,000	26,000
General and administrative	689,000	754,000
Depreciation and amortization	<u>164,000</u>	<u>160,000</u>
Total expenses	2,274,000	2,084,000
Loss from operations	(2,119,000)	(2,064,000)
Other income (expense)		
Interest and miscellaneous income	10,000	33,000
Interest and other expense	<u>(313,000)</u>	<u>(320,000)</u>
	(303,000)	(287,000)
Net loss	\$ (2,422,000)	\$ (2,351,000)
Basic and diluted loss per common share	<u>\$ (0.16)</u>	<u>\$ (0.17)</u>
Weighted average basic and diluted common shares outstanding	<u>15,524,734</u>	<u>14,200,273</u>
Net loss	\$ (2,422,000)	\$ (2,351,000)
Other comprehensive income (loss)		
Foreign currency translation adjustment	<u>(8,000)</u>	<u>10,000</u>
Comprehensive loss	\$ (2,430,000)	\$ (2,341,000)

The accompanying notes are an integral part of these statements.

[Table of Contents](#)**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Three Months ended March 31,	
	2005	2004
Cash flows from operating activities:		
Net loss	\$ (2,422,000)	\$ (2,351,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Warrants issued in payment of consulting expenses	—	42,000
Amortization of restricted stock grants	32,000	29,000
Depreciation and amortization	164,000	160,000
Amortization of debt costs	46,000	46,000
Change in operating assets and liabilities:		
Accounts receivable	27,000	(40,000)
Inventory	12,000	—
Prepaid expenses and other current assets	136,000	(113,000)
Restricted cash and other assets	553,000	30,000
Accounts payable and accrued expenses	(331,000)	(125,000)
Accrued interest payable	261,000	261,000
Deferred revenues	229,000	(4,000)
Net cash used in operating activities	<u>(1,293,000)</u>	<u>(2,065,000)</u>
Cash flows from investing activities:		
Capital expenditures	(10,000)	(60,000)
Redemptions of short term investments and certificates of deposit	14,000	921,000
Net cash provided by investing activities	<u>4,000</u>	<u>861,000</u>
Cash flows from financing activities:		
Payments of notes payable	(223,000)	(225,000)
Proceeds from secured notes payable	2,633,000	—
Proceeds from stock issuances, net of costs of \$647,000	—	9,035,000
Net cash provided by financing activities	<u>2,410,000</u>	<u>8,810,000</u>
Net increase in cash and cash equivalents	1,121,000	7,606,000
Effect of exchange rate changes on cash	(8,000)	23,000
Cash and cash equivalents at beginning of period	1,775,000	727,000
Cash and cash equivalents at end of period	<u>\$ 2,888,000</u>	<u>\$ 8,356,000</u>
<i>Cash paid for interest</i>	\$ 7,000	\$ 6,000
<i>Supplemental disclosure of non-cash transactions 200,000 shares of common stock issued pursuant to the Standby Equity Distribution Agreement and 7% Secured Convertible Debentures</i>	\$ 500,000	\$ —

The accompanying notes are an integral part of these statements.

Access Pharmaceuticals, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

Three Months Ended March 31, 2005 and 2004
(unaudited)**(1) Interim Financial Statements**

The consolidated balance sheet as of March 31, 2005 and the consolidated statements of operations and cash flows for the three months ended March 31, 2005 and 2004 were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these interim financial statements be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2004. The results of operations for the period ended March 31, 2005 are not necessarily indicative of the operating results which may be expected for a full year.

(2) Cash and Cash Equivalents

Cash and cash equivalents includes \$2,360,000, kept in an overnight escrow account, pursuant to the Securities Purchase Agreement with Cornell Capital Partners and Highgate House funds, executed on March 30, 2005.

(3) Intangible Assets

Intangible assets consist of the following (in thousands):

	March 31, 2005		December 31, 2004	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
Amortizable intangible assets				
Patents	\$ 3,179	\$ 948	\$ 3,179	\$ 864
Licenses	500	387	500	375
Total	<u>\$ 3,679</u>	<u>\$ 1,335</u>	<u>\$ 3,679</u>	<u>\$ 1,239</u>

Amortization expense related to intangible assets totaled \$96,000 and \$105,000 for each of the three months ended March 31, 2005 and 2004, respectively. The aggregate estimated amortization expense for intangible assets remaining as of March 31 is as follows (in thousands):

2005	\$ 291
2006	388
2007	363
2008	338
2009	338
Thereafter	<u>626</u>
Total	<u>\$ 2,344</u>

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(4) **Stock-Based Compensation**

The following table illustrates the effect on net loss and loss per share if we had applied the fair value recognition provisions of FASB Statement 123, *Accounting for Stock-Based Compensation*, using assumptions described in the 2004 Form 10-K, Note 1, to our stock-based employee plans.

	<u>Three months ended March 31,</u>	
	<u>2005</u>	<u>2004</u>
Net loss		
As reported	\$ (2,422,000)	\$ (2,351,000)
Deduct: Stock-based employee compensation expense determined under fair value based method	(155,000)	(212,000)
Pro forma	<u>\$ (2,577,000)</u>	<u>\$ (2,563,000)</u>
Basic and diluted loss per share:		
As reported	\$ (0.16)	\$ (0.17)
Pro forma	(0.17)	(0.18)

The effect of our outstanding options and warrants are anti-dilutive when we have a net loss. The fully diluted shares are:

	<u>Three months ended March 31,</u>	
	<u>2005</u>	<u>2004</u>
Fully diluted shares	21,444,800	20,313,562

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. Other Expenses of Issuance and Distribution

Expenses of the Registrant in connection with the issuance and distribution of the securities being registered, other than the underwriting discount, are estimated as follows:

SEC Registration Fee	\$ 2,052.88
Printing and Engraving Expenses	\$ 5,000
Legal Fees and Expenses	\$ 20,000
Accountants' Fees and Expenses	\$ 20,000
Miscellaneous Costs	\$ 2,000
Total	\$49,052.88

Item 14. Indemnification of Directors and Officers

Section 145 of the Delaware General Corporation law empowers a Delaware corporation to indemnify its officers and directors and certain other persons to the extent and under the circumstances set forth therein.

The Registrant's Certificate of Incorporation, as amended, and By-laws, as amended, provide for indemnification of officers and directors of the Registrant and certain other persons against liabilities and expenses incurred by any of them in certain stated proceedings and under certain stated conditions.

The above discussion of the Registrant's Certificate of Incorporation, as amended, By-laws, as amended, and Section 145 of the Delaware General Corporation Law is not intended to be exhaustive and is qualified in its entirety by such Certificate of Incorporation, By-Laws and statute.

Item 15: Recent Sales of Unregistered Securities

On March 30, 2005, the Registrant entered into a Securities Purchase Agreement with Cornell Capital Partners and Highgate House Funds providing funding in the form of 7% Secured Convertible Debentures due March 2006 for net proceeds of approximately \$2,360,000. The debentures are convertible into an aggregate of 658,259 shares of common stock at any time up to their maturity date. The Registrant also issued the holders of the debentures an aggregate of 50,000 shares of common stock under the terms of the Securities Purchase Agreement.

On March 30, 2005, the Registrant entered into a Standby Equity Distribution Agreement with Cornell Capital Partners, LP. Pursuant to the Standby Equity Distribution Agreement, the Registrant may, at its discretion, periodically issue and sell to Cornell Capital Partners shares of common stock for a total purchase price of \$15.0 million. Cornell Capital Partners will pay the Registrant 98% of, or a 2% discount to, the lowest volume weighted average price of the Registrant's common stock during the five consecutive trading day period immediately following the date the Registrant notifies Cornell Capital Partners that its desires to access the Standby Equity Distribution Agreement. Of each advance made by the Company, Cornell Capital Partners shall retain 3.5% of each advance. Cornell Capital Partners also received a one-time commitment fee in the form of 146,500 shares of common stock. The Registrant also issued 3,500 shares of common stock on March 30, 2005 to Newbridge Securities Corporation, an unaffiliated registered broker-dealer, for services provided under a Placement Agent Agreement.

On February 24, 2004, the Registrant closed a private placement sale of common stock pursuant to which it sold 1,789,371 shares of our common stock at a per share price of \$5.40. The Registrant received gross proceeds of \$9,663,000 from this sale and had legal and placement-related expenses of \$647,000. The investors also received 5 year warrants at an exercise price of \$7.10 per share to purchase 447,344 shares of our common stock and the placement agents received warrants in the offering at an exercise price of \$5.40 per share to purchase 156,481 shares of our common stock.

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All of the above-described issuances were exempt from registration pursuant to Section 4(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder, as transactions not involving a public offering.

Item 16. Exhibits and Financial Statement Schedules

The following is a list of exhibits filed as a part of this registration statement:

- 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 Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
- 3.0 Articles of incorporation and bylaws:
- 3.1 Certificate of Incorporation (Incorporated by Reference to Exhibit 3(a) of our Form 8-B dated July 12, 1989, Commission File Number 9-9134)
- 3.2 Certificate of Amendment of Certificate of Incorporation filed August 21, 1992
- 3.3 Certificate of Merger filed January 25, 1996. (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
- 3.4 Certificate of Amendment of Certificate of Incorporation filed January 25, 1996. (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
- 3.5 Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 of our Form 10-Q for the quarter ended June 30, 1996)
- 3.6 Certificate of Amendment of Certificate of Incorporation filed July 18, 1996. (Incorporated by reference to Exhibit 3.8 of our Form 10-K for the year ended December 31, 1996)
- 3.7 Certificate of Amendment of Certificate of Incorporation filed June 18, 1998. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended June 30, 1998)
- 3.8 Certificate of Amendment of Certificate of Incorporation filed July 31, 2000. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended March 31, 2001)
- 3.9 Certificate of Designations of Series A Junior Participating Preferred Stock filed November 7, 2001 (Incorporated by reference to Exhibit 4.1.h of our Registration Statement on Form S-8, dated December 14, 2001, Commission File No. 333-75136)
- 5† Legal opinion of Bingham McCutchen LLP.
- 10.0 Material contracts:
- 10.1 Irrevocable Assignment of Proprietary Information with Dr. Charles G. Smith (Incorporated by reference to Exhibit 10.6 of our Form 10-K for the year ended December 31, 1991)
- 10.2 Asset Purchase and Royalty Agreement between Block Drug Company, Inc. and us dated June 7, 1995 (Incorporated by reference to Exhibit 10.28 of our Form 10-Q for the quarter ended June 30, 1995)
- 10.3 1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
- 10.4 Patent Purchase Agreement dated April 5, 1994 between David F. Ranney and Access Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.16 of the Form 10-K for the year ended December 31, 1995)
- 10.5 First Amendment to Patent Purchase Agreement dated January 23, 1996 between David F. Ranney and us (Incorporated by reference to Exhibit 10.17 of our Form 10-K for the year ended December 31, 1995)
- 10.6 Lease Agreement between Pollock Realty Corporation and us dated July 25, 1996 (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended September 30, 1996)
- 10.7 Platinate HPMa Copolymer Royalty Agreement between The School of Pharmacy, University of London and the Company dated November 19, 1996 (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended September 30, 1996)

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- 10.8 Agreement of Merger and Plan of Reorganization, dated May 23, 1997 among us, Access Holdings, Inc and Tacora Corporation (Incorporated by reference to Exhibit 10.11 of the Company's Form 10-K for the year ended December 31, 1997)
- 10.9 License Agreement between ProStrakan Limited and us dated February 26, 1998 (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.12 of our Form 10-Q for the quarter ended March 31, 1998)
- 10.10 Agreement between us and Block Drug Company, Inc. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.13 of our Form 10-Q for the quarter ended June 30, 1998)
- 10.11* Employment Agreement of Mr. Kerry P. Gray (Incorporated by reference to our Registration Statement on Form SB-2 dated January 11, 1999, Commission File No. 333-62463)
- 10.12 Letter Agreement between us and David F. Ranney (Incorporated by reference to our Registration Statement on Form SB-2 dated January 11, 1999, Commission File No. 333-62463)
- 10.13 License Agreement between Block Drug Company and us dated December 21, 1998 (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.11 of our Form 10-K for the year ended December 31, 1998)
- 10.14 Agreement of Merger and Plan of Reorganization, dated as of February 23, 1999 among us, Access Holdings, Inc. and Virologix Corporation (Incorporated by reference to Exhibit 2.2 of the Company's Form 8-K filed on August 3, 1999)
- 10.15* Employment Agreement of David P. Nowotnik, PhD (Incorporated by reference to Exhibit 10.19 of our Form 10-K for the year ended December 31, 1999)
- 10.16* 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10K for the year ended December 31, 1999)
- 10.17* 2000 Special Stock Option Plan and Agreement (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)
- 10.18 Form of Convertible Note (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)
- 10.19 Supplemental Lease Agreement between Pollock Realty Corporation and us dated February 9, 2002. (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended June 30, 2002)
- 10.20 Rights Agreement, dated as of October 31, 2001 between the Registrant and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 99.1 of our Current Report on Form 8-K dated October 19, 2001)
- 10.21* 2001 Restricted Stock Plan (incorporated by reference to Appendix A of our Proxy Statement filed on April 16, 2001)
- 10.22 Supplemental Lease Agreement between Pollock Realty Corporation and us dated September 15, 2002. (Incorporated by reference to Exhibit 10.24 of our Form 10-K for the year ended December 31, 2001)
- 10.23* Amendment to 1995 Stock Option Plan (Incorporated by reference to Exhibit 10.25 of our Form 10-K for the year ended December 31, 2001).
- 10.24 Asset Sale Agreement among BIOA Pty. Limited, Access Pharmaceuticals Australia Pty. Limited, Human Therapeutics Limited and us dated February 26, 2002. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.26 of our Form 10-Q for the quarter ended March 31, 2002)
- 10.25 Asset Sale Agreement between Block Drug Company, Inc. and us dated July 22, 2002. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.27 of our Form 10-Q for the quarter ended September 30, 2002)
- 10.26 License and Supply Agreement between Wyeth, acting through its Wyeth Consumer Healthcare Division and us dated January 6, 2004. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.26 of our Form 10-Q for the quarter ended March 31, 2004)
- 10.27 Standby Equity Distribution Agreement dated March 30, 2005 between Cornell Capital Partners, LP and the Registrant (incorporated by reference from Exhibit 10.27 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.28 Securities Purchase Agreement date March 30, 2005 between Buyers and the Registrant (incorporated by reference from Exhibit 10.28 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).

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- 10.29 Secured Convertible Notes (incorporated by reference from Exhibit 10.29 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.30 Investor Rights Agreement (incorporated by reference from Exhibit 10.30 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.31 Security Agreement (incorporated by reference from Exhibit 10.31 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.32 Pledge and Escrow Agreement (incorporated by reference from Exhibit 10.32 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.33 Escrow Agreement (incorporated by reference from Exhibit 10.33 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.34 Registration Rights Agreement (incorporated by reference from Exhibit 10.34 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.35*† Separation Agreement between Kerry P. Gray and the Registrant, dated as of May 10, 2005.
- 10.36*† Letter Agreement between Rosemary Mazanet, M.D., Ph.D, dated as of May 10, 2005.
- 10.37* 2005 Equity Incentive Plan (incorporated by reference from Exhibit 2 of the Registrant's Proxy Statement filed April 18, 2005).
- 21† Subsidiaries of the Registrant
- 23.0† Consent of Bingham McCutchen LLP (included in Exhibit 5)
- 23.1 Consent of Grant Thornton LLP

* Management contract or compensatory plan.

† Filed previously.

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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:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933.

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration.

(iii) 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, as amended, the Registrant has duly caused this Amendment No. 1 to Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Dallas, State of Texas, on this 10th day of June, 2005.

ACCESS PHARMACEUTICALS, INC.

Date June 10, 2005

By: /s/ Rosemary Mazanet
Rosemary Mazanet
Acting Chief Executive Officer

Date June 10, 2005

By: /s/ Stephen B. Thompson
Stephen B. Thompson
Vice President, Chief Financial Officer
and Treasurer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 1 to Registration Statement on Form S-1 has been signed below by the following persons in the capacities and on the dates indicated:

Date June 10, 2005

By: /s/ Rosemary Mazanet
Rosemary Mazanet
Acting Chief Executive Officer, and Director
(Principal Executive Officer)

Date June 10, 2005

By: /s/ Stephen B. Thompson
Stephen B. Thompson
Vice President, Chief Financial Officer and
Director
(Principal Financial and Accounting Officer)

Date June 10, 2005

By: *
Stuart M. Duty, Director

Date June 10, 2005

By: *
J. Michael Flinn, Director

Date June 10, 2005

By: *
Stephen B. Howell, Director

Date June 10, 2005

By: *
Max Link, Director

Date June 10, 2005

By: *
Herbert H. McDade, Jr., Director

Date June 10, 2005

By: *
John J. Meakem, Jr., Director

* /s/ Stephen B Thompson
Stephen B. Thompson
Attorney-in-Fact

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EXHIBIT INDEX

The following is a list of exhibits filed as a part of this registration statement:

- 2.2 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 Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
- 4.0 Articles of incorporation and bylaws:
 - 3.1 Certificate of Incorporation (Incorporated by Reference to Exhibit 3(a) of our Form 8-B dated July 12, 1989, Commission File Number 9-9134)
 - 3.2 Certificate of Amendment of Certificate of Incorporation filed August 21, 1992
 - 3.3 Certificate of Merger filed January 25, 1996. (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
 - 3.4 Certificate of Amendment of Certificate of Incorporation filed January 25, 1996. (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
 - 3.5 Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 of our Form 10-Q for the quarter ended June 30, 1996)
 - 3.6 Certificate of Amendment of Certificate of Incorporation filed July 18, 1996. (Incorporated by reference to Exhibit 3.8 of our Form 10-K for the year ended December 31, 1996)
 - 3.7 Certificate of Amendment of Certificate of Incorporation filed June 18, 1998. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended June 30, 1998)
 - 3.9 Certificate of Amendment of Certificate of Incorporation filed July 31, 2000. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended March 31, 2001)
 - 3.9 Certificate of Designations of Series A Junior Participating Preferred Stock filed November 7, 2001 (Incorporated by reference to Exhibit 4.1.h of our Registration Statement on Form S-8, dated December 14, 2001, Commission File No. 333-75136)
- 5† Legal opinion of Bingham McCutchen LLP
- 10.0 Material contracts:
 - 10.1 Irrevocable Assignment of Proprietary Information with Dr. Charles G. Smith (Incorporated by reference to Exhibit 10.6 of our Form 10-K for the year ended December 31, 1991)
 - 10.2 Asset Purchase and Royalty Agreement between Block Drug Company, Inc. and us dated June 7, 1995 (Incorporated by reference to Exhibit 10.28 of our Form 10-Q for the quarter ended June 30, 1995)
 - 10.3 1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
 - 10.4 Patent Purchase Agreement dated April 5, 1994 between David F. Ranney and Access Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.16 of the Form 10-K for the year ended December 31, 1995)
 - 10.5 First Amendment to Patent Purchase Agreement dated January 23, 1996 between David F. Ranney and us (Incorporated by reference to Exhibit 10.17 of our Form 10-K for the year ended December 31, 1995)
 - 10.6 Lease Agreement between Pollock Realty Corporation and us dated July 25, 1996 (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended September 30, 1996)
 - 10.7 Platinate HEMA Copolymer Royalty Agreement between The School of Pharmacy, University of London and the Company dated November 19, 1996 (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended September 30, 1996)
 - 10.8 Agreement of Merger and Plan of Reorganization, dated May 23, 1997 among us, Access Holdings, Inc and Tacora Corporation (Incorporated by reference to Exhibit 10.11 of the Company's Form 10-K for the year ended December 31, 1997)
 - 10.9 License Agreement between ProStrakan Limited and us dated February 26, 1998 (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.12 of our Form 10-Q for the quarter ended March 31, 1998)

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- 10.10 Agreement between us and Block Drug Company, Inc. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.13 of our Form 10-Q for the quarter ended June 30, 1998)
- 10.11* Employment Agreement of Mr. Kerry P. Gray (Incorporated by reference to our Registration Statement on Form SB-2 dated January 11, 1999, Commission File No. 333-62463)
- 10.12 Letter Agreement between us and David F. Ranney (Incorporated by reference to our Registration Statement on Form SB-2 dated January 11, 1999, Commission File No. 333-62463)
- 10.13 License Agreement between Block Drug Company and us dated December 21, 1998 (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.11 of our Form 10-K for the year ended December 31, 1998)
- 10.14 Agreement of Merger and Plan of Reorganization, dated as of February 23, 1999 among us, Access Holdings, Inc. and Virologix Corporation (Incorporated by reference to Exhibit 2.2 of the Company's Form 8-K filed on August 3, 1999)
- 10.15* Employment Agreement of David P. Nowotnik, PhD (Incorporated by reference to Exhibit 10.19 of our Form 10-K for the year ended December 31, 1999)
- 10.16* 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10K for the year ended December 31, 1999)
- 10.17* 2000 Special Stock Option Plan and Agreement (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)
- 10.21 Form of Convertible Note (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)
- 10.22 Supplemental Lease Agreement between Pollock Realty Corporation and us dated February 9, 2002. (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended June 30, 2002)
- 10.23 Rights Agreement, dated as of October 31, 2001 between the Registrant and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 99.1 of our Current Report on Form 8-K dated October 19, 2001)
- 10.21* 2001 Restricted Stock Plan (incorporated by reference to Appendix A of our Proxy Statement filed on April 16, 2001)
- 10.22 Supplemental Lease Agreement between Pollock Realty Corporation and us dated September 15, 2002. (Incorporated by reference to Exhibit 10.24 of our Form 10-K for the year ended December 31, 2001)
- 10.23* Amendment to 1995 Stock Option Plan (Incorporated by reference to Exhibit 10.25 of our Form 10-K for the year ended December 31, 2001).
- 10.24 Asset Sale Agreement among BIOA Pty. Limited, Access Pharmaceuticals Australia Pty. Limited, Human Therapeutics Limited and us dated February 26, 2002. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.26 of our Form 10-Q for the quarter ended March 31, 2002)
- 10.25 Asset Sale Agreement between Block Drug Company, Inc. and us dated July 22, 2002. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.27 of our Form 10-Q for the quarter ended September 30, 2002)
- 10.26 License and Supply Agreement between Wyeth, acting through its Wyeth Consumer Healthcare Division and us dated January 6, 2004. (Certain portions are subject to a grant of confidential treatment) (Incorporated by reference to Exhibit 10.26 of our Form 10-Q for the quarter ended March 31, 2004)
- 10.27 Standby Equity Distribution Agreement dated March 30, 2005 between Cornell Capital Partners, LP and the Registrant (incorporated by reference from Exhibit 10.27 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.28 Securities Purchase Agreement date March 30, 2005 between Buyers and the Registrant (incorporated by reference from Exhibit 10.28 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.29 Secured Convertible Notes (incorporated by reference from Exhibit 10.29 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.30 Investor Rights Agreement (incorporated by reference from Exhibit 10.30 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.31 Security Agreement (incorporated by reference from Exhibit 10.31 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).

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- 10.32 Pledge and Escrow Agreement (incorporated by reference from Exhibit 10.32 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.33 Escrow Agreement (incorporated by reference from Exhibit 10.33 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.34 Registration Rights Agreement (incorporated by reference from Exhibit 10.34 of the Registrant's Form 10-Q for the quarter ended March 31, 2005).
- 10.35*† Separation Agreement between Kerry P. Gray and the Registrant, dated as of May 10, 2005.
- 10.36*† Letter Agreement between Rosemary Mazanet, M.D., Ph.D, dated as of May 10, 2005.
- 10.37* 2005 Equity Incentive Plan (incorporated by reference from Exhibit 2 of the Registrant's Proxy Statement filed April 18, 2005).
- 21† Subsidiaries of the Registrant
- 23.0† Consent of Bingham McCutchen LLP (included in Exhibit 5)
- 23.1 Consent of Grant Thornton LLP

* Management contract or compensatory plan.

† Filed previously.

EXHIBIT 23.1

CONSENT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM

We have issued our report dated March 31, 2005, accompanying the consolidated financial statements of Access Pharmaceuticals, Inc. contained in the Registration Statement and Prospectus. We have also issued our report dated March 31, 2005, on management's assessment of the effectiveness of internal control over financial reporting included in the Annual Report on Form 10-K for the year ended December 31, 2004. We consent to the use of the aforementioned reports in the Registration Statement and Prospectus, and to the use of our name as it appears under the caption "Experts."

/s/ Grant Thornton LLP
Grant Thornton LLP

Dallas, Texas
June 10, 2005