

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

FORM 10-Q

/X/ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2005

Commission File Number 0-9314

ACCESS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

83-0221517

(State of Incorporation)

(I.R.S. Employer I.D. No.)

2600 Stemmons Frwy, Suite 176, Dallas, TX 75207

(Address of principal executive offices)

Telephone Number (214) 905-5100

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirement for the past 90 days.

Yes No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The number of shares outstanding of the issuer's common stock, as of August 9, 2005, was 15,722,552 shares, \$0.01 par value per share.

Total No. of Pages 31

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PART I -- FINANCIAL INFORMATION

Risk Factors

This Quarterly Report on Form 10-Q contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, 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, our ability to repay or restructure our outstanding debt obligations, 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 Form 10-Q, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission. Forward-looking statements contained in this Form 10-Q include, but are not limited to those relating to anticipated product approvals and timing thereof, the terms of future licensing arrangements, our ability to secure additional financing for our operations, our ability to repay our outstanding debt obligations, our ability to fund our operations through August 31, 2005, and our expected capital expenditures.

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

We currently have liquid assets to allow us to continue operations through August 31, 2005, assuming the receipt of accounts receivable currently due and assuming no receipt of funds from any financing transactions, including selling equity securities in connection with our Standby Equity Distribution Agreement (the "SEDA") with Cornell Capital. We anticipate that we will be able to raise additional funds by selling equity securities in connection with our SEDA with Cornell Capital, subject to the terms of the SEDA and our ability to adhere to the terms of the SEDA. By selling equity,

the relative equity ownership of our existing investors would be diluted and the new investors could obtain terms more favorable than previous investors. Further, we have issued an aggregate of \$13,530,000 of convertible subordinated 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, we have issued \$2,633,000 of Secured Convertible Notes due March 31, 2006 with initial partial repayment commencing in November 2005. Such Secured Convertible Notes 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. A failure to restructure our convertible notes or obtain additional funding to repay the convertible notes and support our working capital and operating requirements, would cause us to be in default of our convertible notes, prevent us from making expenditures that are needed to allow us to maintain our operations and would allow our convertible noteholders to exercise their remedies under the note instruments.

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We are in negotiations to sell certain assets to provide additional liquidity. We are also in negotiations with holders of our convertible notes due September 2005 to restructure such notes. There can be no assurance that we will be successful in our efforts to sell assets or that we will be able to successfully restructure such notes.

At this time we would not be able to draw funds from timely from the SEDA, due to the terms of the SEDA, in an amount sufficient to repay our outstanding debt obligations when they come due.

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 (plus interest due on such date of \$1,042,000), \$5.5 million of our Convertible Subordinated Notes due in September 2008 and \$2,633,000 of our Secured Convertible Notes due in March 2006 with initial partial repayment commencing in November 2005.

If our cash flow is inadequate to meet these obligations, we will default on the notes. Any default on the notes could allow our note holders to foreclose upon our assets, force us into bankruptcy or our secured note holders could foreclose on the escrow and pledge of our shares and sell the shares on the open market, which is likely to cause a significant drop in the price of our stock.

We may be unable to repay or repurchase or restructure the Secured Convertible Notes due in March 2006 and convertible subordinated notes due in September 2005 and September 2008 and be forced into bankruptcy. A default on our convertible notes due September 13, 2005 would cause a cross-default on our convertible notes due March 2006 and September 2008. In the event of a default, the holders of our secured convertible notes have the right to foreclose on all of our assets, which could force us to curtail or cease our business operations.

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 \$2,633,000 Secured Convertible Notes are secured by all of our assets. As a result, if a cross-default is caused by our default on the convertible notes due September 13, 2005 or if we default under the terms of the Secured Convertible Notes or related agreements, including our failure to issue shares of common stock upon conversion by the holder, our failure to maintain the effectiveness of a registration statement, breach of any covenant, representation or warranty in the Securities Purchase Agreement or related Secured Convertible Notes or the commencement of a bankruptcy, insolvency, reorganization or liquidation proceeding against the Company could require the early repayment of the Secured Convertible Notes, 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 the assets of the

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Company 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 have limited liquid assets.

We currently have liquid assets sufficient to fund our operations only through August 31, 2005, assuming the receipt of account receivable currently due. If we are unable to secure financing prior to the exhaustion of our liquid assets we may be required to cease or curtail our operations.

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 \$70.7 million through June 30, 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 if we expand research and development efforts and preclinical and clinical trials.

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(R) or OraDisc(TM) 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.

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 \$6.2 million for the six month period ended June 30, 2005, \$4.9 million for the six month period ended June 30, 2004, \$9.1 million for the year ended December 31, 2004 and \$8.2 million for the year ended December 31, 2003.

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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, consolidate or sell assets to other entities
- - create additional liens on our assets.

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.

AMEX listing requirements.

Our common stock is presently listed on the American Stock Exchange 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 Notes and the SEDA 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 the AMEX stockholders' equity standard as of June 30, 2005. However, we have until December 31, 2005 to become compliant with such equity standard. If we are unable to remedy any listing standard noncompliance with AMEX under its regulations, or otherwise regain compliance, and within the required time frames for such remediation, or otherwise regain compliance, or if we default on our debt obligations we cannot assure investors that our common stock will continue to remain eligible for listing on AMEX. In the event that our common stock is delisted from AMEX its market value and liquidity could be materially adversely affected.

Our Standby Equity Distribution Agreement may have a dilutive impact on our stockholders.

We are to a great extent dependent on external financing to fund our operations. Our financial needs may be partially provided from the SEDA. The issuance of shares of our common stock under the SEDA 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. In addition, if we access the SEDA, we will issue shares of our common stock to Cornell Capital Partners at a discount of 2% of the lowest daily volume weighted average of our common stock during a specified period of trading days after we access the SEDA. Issuing shares at a

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discount will further dilute the interests of other stockholders and may negatively affect the market price of our Common Stock.

To the extent that Cornell sells shares of our common stock issued under SEDA to third parties, our stock price may decrease due to the additional selling pressure in the market. The perceived risk of dilution from sales of stock to or by Cornell may cause holders of our common stock to sell their shares, or it may encourage short sales of our common stock or other similar transactions. This could contribute to a decline in the stock price of our common stock.

At this time we would not be able to draw funds from the SEDA in an amount sufficient to repay our outstanding debt obligations when they come due.

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 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

principal and \$1,042,000 interest on convertible notes which are required to be repaid in September 2005 and \$2,633,000 of Secured Convertible Notes due in March 2006) through August 31, 2005 assuming the receipt of accounts receivable currently due. Even if 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.

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(R) A
 - Discuss Dental, Inc. - United States marketing rights
 - ProStrakan Ltd. - United Kingdom and Ireland manufacturing, marketing rights and regulatory approval
 - Zambon Group - France, Germany, Holland, Belgium, Luxembourg, Switzerland, Brazil, Colombia and Italy manufacturing and marketing rights
 - Laboratories Dr. Esteve SA - Spain, Portugal and Greece 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 for marketing rights
 - Orient Europharma, Co., Ltd. for Taiwan, Hong-Kong, Malaysia, Philippines, Thailand and Singapore for marketing rights

- * Zindaclin(R) and Residerm(R)
 - ProStrakan Ltd. - worldwide manufacturing, marketing and regulatory approval rights
 - Fujisawa GmbH - sublicensed continental Europe marketing rights
 - EpiTan, Ltd. - sublicensed Australia and New Zealand marketing rights
 - Hyundai - sublicensed Korea marketing rights
 - Taro - sublicensed Israel marketing rights
 - Biosintetica - sublicensed Brazil marketing rights
 - Pliva dd Hrvatska d.o.o. - sublicensed Czech, Estonia, Hungary, Latvia, Poland, Slovak and Slovenia marketing rights
 - Five companies for five other smaller countries - sublicensed marketing rights

For one of our OraDisc(TM) 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.

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

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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(R). 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(R) in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004 and in the quarters ended March 31, 2005 and June 30, 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(R) and our ResiDerm(R) 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(R) which is a European Union approved facility. Zindaclin(R) is approved in the UK and throughout Europe in most European Union countries including new member states and several non-European markets. Zindaclin(R) is marketed in the UK, France, Germany, Ireland, Belgium, Cyprus, Israel and Korea. Zindaclin(R) 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(TM) A in September 2004 and are proceeding with our manufacturing and marketing plans for 2006.

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 the Company to enable significant cost savings to be realized.

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:

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- - 5% amlexanox paste is an approved product for sale in the US (Aphthasol(R)); approved in the UK and Canada but not yet sold; approved in ten EU countries but not yet sold;
- - Zindaclin(R) 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(TM) 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 2006.
- - Our other OraDisc(TM) 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 which 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

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clinical trials, even after demonstrating promising results in earlier trials. In particular, OraDisc(TM) and polymer platinate have taken longer to progress through clinical trials than originally planned. 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 which we have developed, manufactured or sold and any such product liability claim could adversely affect our business, operating results or financial condition.

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

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

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

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions.

The following products may compete with polymer platinate:

-- Cisplatin, marketed by Bristol-Myers-Squibb, the originator of the drug, and several generic manufacturers;

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-- 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 platinate:

-- 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(R) products:

-- 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(R) 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 which 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.

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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(R) and Zindaclin(R) 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.

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(R) in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004 as well as the quarters ended March 31, 2005 and June 30, 2005.

We received regulatory approval from the FDA to manufacture and sell OraDisc(TM) A in September 2004 and are proceeding with our manufacturing and marketing plans for 2006.

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

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- - 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(R) and Residerm(R) between 2007 and 2011
- OraDisc(TM) 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 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.

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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, and we may be unsuccessful in attracting and retaining these personnel.

Ownership of our shares is concentrated, to some extent, in the hands of a few 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 June 30, 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, including in connection with the SEDA. Substantially, all of the 15,722,552 shares of our common stock that are outstanding as of August 8, 2005, are unrestricted and freely tradable or tradable pursuant to a resale registration statement or under Rule 144 of the Securities Act.

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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.

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 systems 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. 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 an effective internal control system environment 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.

ITEM 1 FINANCIAL STATEMENTS

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

ITEM 2 MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, 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 Form 10-Q, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission. Forward-looking statements contained in this Form 10-Q include, but are not limited to those relating to anticipated product approvals and timing thereof, the terms of future

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licensing arrangements, our ability to secure additional financing for our operations, our ability to repay our outstanding debt obligations, our ability to fund our operations through August 31, 2005, and our expected capital expenditures.

At this time, as a result of current uncertainty with respect to our liquidity position and our inability to currently repay our debt obligations pursuant to our outstanding convertible notes, we are unable to make any projections of our expected revenues in the short and long term.

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,
- mucoadhesive disc technology,
- hydrogel particle aggregate technology, and
- Residerm(R) topical delivery.

In addition, we are marketing in the United States - Aphthasol(R), 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(R). 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(R) in the US market in September 2004 and recorded sales in the third and fourth quarters of 2004 as well as the quarters ended March 31, 2005 and June 30, 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 June 30, 2005, our accumulated deficit was \$70,673,000.

On March 30, 2005, the Company finalized an agreement with Cornell Capital Partners and Highgate House Funds providing funding in the form of Secured Convertible Note for net proceeds of approximately \$2,360,000, and an Equity Distribution Agreement under which, subject to terms of the Agreement, including without limitation limitations relating to timing and amounts of draws and certain AMEX stockholder approval limitations, the Company can draw

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up to \$15,000,000 in working capital over a 2-year period (see further discussion under Risk Factors and Liquidity and Capital Resources).

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 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.

On April 18, 2005 we announced that we executed an exclusive License Agreement granting Discuss 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(R) A, which was approved by the FDA in September 2004 for the same indication. In addition, we granted Discuss Dental the rights to any future product improvements for amlexanox in oral disease. Under the terms of the agreement, Discuss Dental paid an upfront royalty payment of \$500,000 and will pay us a licensing fee make future milestone payments.

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 June 30, 2005 our cash and cash equivalents and short-term investments were \$1,288,000 and our working capital was \$(12,914,000). Our working capital at June 30, 2005 represented a decrease of \$5,126,000 as compared to our working capital as of December 31, 2004 of \$(7,788,000). The decrease in working capital was due mainly to the loss from operations for the six months ended June 30, 2005.

As of June 30, 2005, the Company had a working capital deficit of approximately \$12,914,000. As of that date, the Company did not have enough capital to achieve its near, medium or long-term goals. The Company currently has liquid assets to fund operations through August 31, 2005, assuming the receipt of accounts receivable currently due.

As of March 30, 2005 the Company executed a Standby Equity Distribution Agreement (SEDA) with Cornell Capital Partners. Under the SEDA, subject to terms of the SEDA, including without limitation limitations relating to timing and amounts of draws and certain AMEX shareholder approval requirements, the Company may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to a maximum of \$15,000,000. The purchase price for the shares is equal to their market price, which is defined in the SEDA as 98% of the lowest volume weighted average price of the common stock during a specified period of trading days following the date notice is given by the Company that it desires to access the SEDA. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the SEDA. The amount of each draw down is subject to a maximum amount of \$1,000,000. The terms of

the SEDA 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 \$1.55, we could sell to Cornell Capital approximately \$2,700,000 of our common stock subject to the 9.9% limitation. Thus, in order for the Company to receive all the funding available

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under the SEDA 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. Upon closing of the transaction, Cornell Capital Partners received a one-time commitment fee of 146,500 shares of the Company's common stock. As of the same date, the Company entered into a Placement Agent Agreement with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the Placement Agent Agreement, the Company paid a one-time placement agent fee of 3,500 shares of common stock. If the Company is unable to adhere to the terms of the SEDA, it will not be able to make any draws upon the SEDA.

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, Cornell Capital Partners and Highgate House Funds purchased an aggregate of \$2,633,000 principal amount of Secured Convertible Notes from the Company (net proceeds to the Company of \$2,300,000). The Secured Convertible Notes 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 Note has not been converted to common stock. The Secured Convertible Note 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 Notes are secured by all of the assets of the Company. The Company has the right to redeem the Secured Convertible Notes upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, the Company issued to the holders an aggregate of 50,000 shares of common stock of the Company.

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 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, prevent us from making expenditures that are needed to allow us to maintain our operations and allow our secured note holders to foreclose on our assets or force us into bankruptcy.

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 June 30, 2005 of \$70,673,000. 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 August 31, 2005 assuming the receipt of accounts receivable currently due 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 Convertible Notes in March 2006.

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;
- - our ability to raise financing in order to continue our operations;
- - the successful commercialization of amlexanox and Zindaclin (R);
- - 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.

SECOND QUARTER 2005 COMPARED TO SECOND QUARTER 2004

Our licensing revenue in the second quarter of 2005 was \$24,000, as compared to licensing revenue of \$44,000 in same quarter of 2004, a decrease of \$20,000. 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(R).

There were \$201,000 in product sales of Aphthasol(R) in the second quarter of 2005, as compared to no sales in the second quarter of 2004 due to a supply interruption in such period. Aphthasol(R) product sales recommenced in September 2004.

Royalty income in the second quarter of 2005 was \$24,000, as compared to \$24,000 in the

second quarter of 2004.

Total research spending for the second quarter of 2005 was \$1,440,000, as compared to \$1,281,000 for the same period in 2004, an increase of \$159,000. The increase in expenses was primarily the result of:

- - higher costs (\$132,000) for pre-production of OraDisc(TM) A; and
- - higher costs for product and clinical trials for AP5346 (\$86,000).

The increase in expenses was partially offset by

- - lower salary and related costs due to a reduction in staff (\$52,000).
- - lower costs for other projects (\$7,000).

Our cost of product sales was \$178,000 in the second quarter of 2005, as compared to \$31,000 in the second quarter of 2004, an increase of \$147,000. The increase in cost of product sales was due to increased product sales and fees associated with sales in 2005 versus no sales in 2004 .

Total general and administrative expenses were \$1,816,000 for the second quarter of 2005, an increase of \$1,044,000 as compared to the same period in 2004. The increase in spending was due primarily to the following:

- - expenses due to the separation agreement with our former CEO (\$839,000);
- - royalty license expenses (\$150,000);
- - higher patent expenses (\$22,000); and
- - other net increases (\$33,000).

Depreciation and amortization was \$166,000 for the second quarter of 2005 as compared to \$160,000 for the same period in 2004 reflecting an increase of \$6,000. The increase in depreciation and amortization was due to increased depreciation resulting from the acquisition of additional capital assets.

Total operating expenses in the second quarter of 2005 were \$3,600,000 as compared to total operating expenses of \$2,244,000 for the same period in 2004, an increase of \$1,356,000.

Loss from operations in the second quarter of 2005 was \$3,351,000 as compared to a loss of \$2,176,000 for the same period in 2004, an increase of \$1,175,000.

Interest and miscellaneous income was \$12,000 for the second quarter of 2005 as compared to \$35,000 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 \$447,000 for the second quarter of 2005 as compared to \$412,000 for the same period in 2004, an increase of \$35,000. The increase in expense is due to the addition of the Secured Convertible Notes.

Net loss in the second quarter of 2005 was \$3,786,000, or a \$0.24 basic and diluted loss per common share, compared with a loss of \$2,553,000, or a \$0.17 basic and diluted loss per common share for the same period in 2004, an increased loss of \$1,233,000 in 2005.

Our licensing revenue in the first six months of 2005 was \$35,000, as compared to licensing revenue of \$48,000 in the same period of 2004, a decrease of \$13,000. 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(R).

There were \$318,000 in product sales of Aphthasol(R) in the first six months of 2005, as compared to no sales in the same period of 2004, due to a supply interruption in such period. Aphthasol(R) product sales recommenced in September 2004.

Royalty income for the first six months of 2005 was \$51,000, as compared to \$40,000 in the same period of 2004, an increase of \$11,000.

Total research spending for the first six months of 2005 was \$2,759,000, as compared to \$2,425,000 for the same period in 2004, an increase of \$334,000. The increase in expenses was the result of:

- - higher costs for product and clinical trials for AP5346 (\$192,000);
- - higher costs (\$113,000) for pre-production of OraDisc(TM) A; and
- - higher costs for other projects (\$29,000).

Our cost of product sales was \$280,000 for the first six months of 2005, as compared to \$57,000 in the same period of 2004, an increase of \$223,000. The increase in cost of product sales was due to increased product sales and fees associated with sales in 2005 versus no sales in 2004 .

Total general and administrative expenses were \$2,505,000 for the first six months of 2005, an increase of \$979,000 as compared to the same period in 2004. The increase in general and administrative expenses was due primarily to the following:

- - expenses due to the separation agreement with our former CEO (\$839,000); and
- - royalty license expenses (\$150,000).

The increase in general and administrative expenses is partially offset by other net decreases (\$10,000).

Depreciation and amortization was \$330,000 for the first six months of 2005 as compared to \$320,000 for the same period in 2004 reflecting an increase of \$10,000. 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 six months of 2005 were \$5,874,000 as compared to total operating expenses of \$4,328,000 for the same period in 2004, an increase of \$1,546,000.

Loss from operations in the first six months of 2005 was \$5,470,000 as compared to a loss of \$4,240,000 for the same period in 2004, an increase of \$1,230,000.

Interest and miscellaneous income was \$22,000 for the first six months of 2005 as compared to

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\$68,000 for the same period in 2004, a decrease of \$46,000. The decrease in interest income was due to lower cash balances and lower interest rates in 2005 as compared with 2004.

Interest and other expense was \$760,000 for the first six months of 2005 as compared to \$732,000 for the same period in 2004, an increase of \$28,000. The increase in expense is due to the addition of the

Secured Convertible Notes.

Net loss in the first six months of 2005 was \$6,208,000, or a \$0.40 basic and diluted loss per common share, compared with a loss of \$4,904,000, or a \$0.33 basic and diluted loss per common share for the same period in 2004, an increase of \$1,304,000.

ITEM 3 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 June 30, 2005. We do not believe that we are exposed to any other market risks, as defined under applicable SEC regulations. We are not exposed to risks for changes in commodity prices, or any other market risks.

ITEM 4 CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures. Our chief executive officer and our chief financial officer, after evaluating the effectiveness of our "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-(e) of the Securities and Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this quarterly report, concluded that the Company's disclosure controls and procedures were (1) designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's chief executive officer and chief financial officer by others within those entities, particularly during the period in which this report was being prepared, and (2) effective, in that they provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

(b) Changes in internal controls. Except as set forth below, there were no changes in our internal controls over financial reporting during the quarter ended June 30, 2005 that have materially affected, or are reasonably likely to material affect, our internal controls over financial reporting.

(c) As previously reported in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004 (the "Form 10-K"), our management concluded that our internal

control over financial reporting was effective as of December 31, 2004. However, as disclosed in the Form 10-K, our independent auditors concluded that we have two material weaknesses 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, as set forth in their attestation report in the Form 10-K. Their conclusion also points out that "these material weaknesses did not result in any adjustments to the annual or interim consolidated financial statements" and that "this report does not affect (their) report dated March 31, 2005" reflecting their opinion on the financial statements.

(d) Based on the criteria set forth in their attestation report in the Form 10-K, our independent auditors determined that proper segregation of duties do not exist within our accounting and finance area. While management believes that sufficient controls are in place, and that there is adequate segregation of duties within the business, it recognizes that this is a perceived material weakness and is taking the steps it believes are necessary to mitigate this risk. Management and the Audit Committee has considered the need for ongoing monitoring of internal controls under the Sarbanes-Oxley Act of 2002, as well as strengthening the internal controls of the business by the engagement of an outside accounting/finance consulting firm to perform quarterly procedures 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 the Audit Committee although management will be involved in assisting in determining the scope of the quarterly and annual procedures. Terms and conditions of this engagement are still under consideration.

PART II -- OTHER INFORMATION

ITEM 1 LEGAL PROCEEDINGS

None

ITEM 2 SALES OF UNREGISTERED EQUITY SECURITIES AND USE OF PROCEEDS

None

ITEM 3 DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The annual meeting of stockholders was held on May 12, 2005 in New York, NY. At that meeting the following matters were submitted to a vote of the stockholders of record. The proposals were approved by the stockholders, as follows:

-- Three directors were re-elected for three year terms with the following votes:

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Max Link; 11,803,589- For; and 1,631,783- Withheld Authority
John J. Meakem, Jr.; 13,313,423- For; and 121,949- Withheld Authority

-- The terms of office as a director of Access of each of J. Michael Flinn, Stuart M. Duty, Stephen B.Howell and Herbert H. McDade, Jr. continued after the meeting.

Access Pharmaceuticals, Inc. and Subsidiaries

<TABLE>

<CAPTION>

Condensed Consolidated Balance Sheets

	June 30, 2005 December 31, 2004	
ASSETS	-----	
	(unaudited)	
<S>	<C>	<C>
Current assets		
Cash and cash equivalents	\$ 784,000	\$ 1,775,000
Short term investments, at cost	504,000	486,000
Accounts and other receivables	810,000	791,000
Inventory	61,000	125,000
Prepaid expenses and other current assets	827,000	1,093,000
	-----	-----
Total current assets	2,986,000	4,270,000
Property and equipment, net	930,000	1,040,000
Debt issuance costs, net	790,000	130,000
Patents, net	2,146,000	2,315,000
Licenses, net	100,000	125,000
Goodwill, net	1,868,000	1,868,000
Restricted cash and other assets	408,000	1,342,000
	-----	-----
Total assets	\$ 9,228,000	\$ 11,090,000
	=====	=====
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable and accrued expenses	\$ 2,255,000	\$ 2,131,000
Accrued interest payable	878,000	311,000
Deferred revenues	1,904,000	1,199,000
Current portion of notes payable and other future obligations	10,863,000	8,417,000
	-----	-----
Total current liabilities	15,900,000	12,058,000
Note payable, net of current portion	113,000	193,000
Convertible note	5,500,000	5,500,000
	-----	-----
Total liabilities	21,513,000	17,751,000
	-----	-----
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, 15,722,552 at June 30, 2005 and 15,524,734 at December 31, 2004	157,000	155,000
Additional paid-in capital	59,508,000	59,010,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Unamortized value of restricted stock grants	(209,000)	(309,000)
Treasury stock, at cost - 819 shares	(4,000)	(4,000)
Accumulated other comprehensive loss	(19,000)	(3,000)
Accumulated deficit	(70,673,000)	(64,465,000)
	-----	-----
Total stockholders' deficit	(12,285,000)	(6,661,000)
	-----	-----
Total liabilities and stockholders'		

deficit \$ 9,228,000 \$ 11,090,000

</TABLE>

The accompanying notes are an integral part of these statements.

27

Access Pharmaceuticals, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)

<TABLE>

<CAPTION>

	Three months ended		Six months ended	
	June 30,		June 30,	
	2005	2004	2005	2004
<S>	<C>	<C>	<C>	<C>
Revenues				
Licensing revenues	\$ 24,000	\$ 44,000	\$ 35,000	\$ 48,000
Product sales	201,000	-	318,000	-
Royalty income	24,000	24,000	51,000	40,000
Total revenues	249,000	68,000	404,000	88,000
Expenses				
Research and development	1,440,000	1,281,000	2,759,000	2,425,000
Cost of product sales	178,000	31,000	280,000	57,000
General and administrative	1,816,000	772,000	2,505,000	1,526,000
Depreciation and amortization	166,000	160,000	330,000	320,000
Total expenses	3,600,000	2,244,000	5,874,000	4,328,000
Loss from operations	(3,351,000)	(2,176,000)	(5,470,000)	(4,240,000)
Other income (expense)				
Interest and miscellaneous income	12,000	35,000	22,000	68,000
Interest and other expense	(447,000)	(412,000)	(760,000)	(732,000)
	(435,000)	(377,000)	(738,000)	(664,000)
Net loss	\$(3,786,000)	\$(2,553,000)	\$(6,208,000)	\$(4,904,000)

Basic and diluted loss

per common share \$(0.24) \$(0.17) \$(0.40) \$(0.33)

Weighted average basic and diluted common shares

outstanding 15,724,710 15,449,603 15,626,379 14,824,938

Net loss \$(3,786,000) \$(2,553,000) \$(6,208,000) \$(4,904,000)

Other comprehensive loss

Foreign currency translation adjustment (8,000) (25,000) (16,000) (15,000)

Comprehensive loss \$(3,794,000) \$(2,578,000) \$(6,224,000) \$(4,919,000)

</TABLE>

The accompanying notes are an integral part of these statements.

28

Access Pharmaceuticals, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(unaudited)

<TABLE>
<CAPTION>

	Six Months ended June 30,	
	2005	2004
<S>	<C>	<C>
Cash flows from operating activities:		
Net loss	\$(6,208,000)	\$(4,904,000)
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	100,000	60,000
Depreciation and amortization	330,000	320,000
Amortization of debt costs	175,000	92,000
Change in operating assets and liabilities:		
Accounts receivable	(19,000)	21,000
Inventory	64,000	-
Prepaid expenses and other current assets	266,000	37,000
Restricted cash and other assets	581,000	158,000
Accounts payable and accrued expenses	124,000	(586,000)
Accrued interest payable	567,000	521,000
Deferred revenues	705,000	(7,000)
Net cash used in operating activities	(3,315,000)	(4,246,000)
Cash flows from investing activities:		
Capital expenditures	(26,000)	(87,000)
Redemptions of short term investments and certificates of deposit	-	891,000
Net cash provided by (used in) investing activities	(26,000)	804,000
Cash flows from financing activities:		
Payments of notes payable	(267,000)	(249,000)
Proceeds from secured notes payable	2,633,000	-
Proceeds from stock issuances, net of costs of \$647,000	-	9,130,000
Net cash provided by financing activities	2,366,000	8,881,000
Net increase (decrease) in cash and cash equivalents	(975,000)	5,439,000
Effect of exchange rate changes on cash	(16,000)	(18,000)
Cash and cash equivalents at beginning of period	1,775,000	727,000
Cash and cash equivalents at end of period	\$784,000	\$6,148,000
Cash paid for interest	\$10,000	\$15,000
Supplemental disclosure of non-cash transactions		
200,000 shares of common stock issued pursuant to the SEDA and Secured Convertible Notes	\$500,000	\$-
Value of restricted stock grants	-	136,000

</TABLE>

The accompanying notes are an integral part of these statements.

The consolidated balance sheet as of June 30, 2005 and the consolidated statements of operations for the three and six months ended June 30, 2005 and 2004 and the consolidated statements of cash flows for the six months ended June 30, 2005 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 June 30, 2005 are not necessarily indicative of the operating results which may be expected for a full year. The consolidated balance sheet as of December 31, 2004 contains financial information taken from the audited financial statements as of that date.

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.

(2) Intangible Assets

Intangible assets consist of the following (in thousands):

<TABLE>
<CAPTION>

	June 30, 2005		December 31, 2004	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
<S>	<C>	<C>	<C>	<C>
Amortizable intangible assets				
Patents	\$3,179	\$1,033	\$3,179	\$ 864
Licenses	500	400	500	375
Total	\$3,679	\$1,433	\$3,679	\$1,239

</TABLE>

Amortization expense related to intangible assets totaled \$96,000 and \$105,000 for each of the three months ended June 30, 2005 and 2004, respectively and totaled \$194,000 and \$210,000 for the six months ended June 30, 2005 and 2004, respectively. The aggregate estimated amortization expense for intangible assets remaining as of June 30 is as follows (in thousands):

2006	388
2007	363
2008	338
2009	338
Thereafter	626

Total	\$2,246
=====	

(3) 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 Form 10-K, Note 1, to our stock-based employee plans.

<TABLE>
<CAPTION>

	Three months ended June 30, Six months ended June 30,			
	-----		-----	
	2005	2004	2005	2004

<S>	<C>	<C>	<C>	<C>
Net loss as reported	\$(3,786,000)	\$(2,553,000)	\$(6,208,000)	\$(4,904,000)
Deduct: Stock-based employee compensation expense determined under fair value based method	(490,000)	(185,000)	(645,000)	(397,000)
Pro forma	\$(4,276,000)	\$(2,738,000)	\$(6,853,000)	\$(5,301,000)
=====				
Basic and diluted loss per share:				
As reported	\$(0.24)	\$(0.17)	\$(0.40)	\$(0.33)
Pro forma	(0.27)	(0.18)	(0.44)	(0.36)

</TABLE>

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

	Three months ended June 30, Six months ended June 30,			
	-----		-----	
	2005	2004	2005	2004

Fully diluted shares	24,718,707	21,499,919	24,620,376	20,875,274

CERTIFICATION

I, Rosemary Mazanet, the Acting Chief Executive Officer of Access Pharmaceuticals, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Access Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and

d. Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the

registrant's internal control over financial reporting.

Date: August 9, 2005

/s/ Rosemary Mazaanet

Rosemary Mazanet

Acting Chief Executive Officer

CERTIFICATION

I, Stephen B. Thompson, the Chief Financial Officer of Access Pharmaceuticals, Inc., certify that:

1. I have reviewed this quarterly report on Form 10-Q of Access Pharmaceuticals, Inc.;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and

d. Disclosed in this quarterly report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the

registrant's internal control over financial reporting.

Date: August 9, 2005

/s/ Stephen B. Thompson

Stephen B. Thompson
Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002

The certification set forth below is hereby made solely for the purpose of satisfying the requirements of Section 906 of the Sarbanes-Oxley Act of 2002 and may not be relied upon or used for any other purposes.

In connection with the Quarterly Report of Access Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Rosemary Mazanet, Acting Chief Executive Officer certify pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that to my knowledge (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Signed at the City of Dallas, in the State of Texas, this 9th day of August, 2005.

/s/ Rosemary Mazanet

Rosemary Mazanet
Acting Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002

The certification set forth below is hereby made solely for the purpose of satisfying the requirements of Section 906 of the Sarbanes-Oxley Act of 2002 and may not be relied upon or used for any other purposes.

In connection with the Quarterly Report of Access Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2005, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen B. Thompson, Chief Financial Officer certify pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that to my knowledge (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Signed at the City of Dallas, in the State of Texas, this 9th day of August, 2005.

/s/ Stephen B. Thompson

Stephen B. Thompson
Chief Financial Officer