

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, 2004

Commission File Number 0-9314

ACCESS PHARMACEUTICALS, INC.

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(Exact name of registrant as specified in its charter)

Delaware

83-0221517

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(State of Incorporation)

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

2600 Stemmons Frwy, Suite 176, Dallas, TX 75207

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(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 X No

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

Yes X No

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The number of shares outstanding of the issuer's common stock, as of August 13, 2004, was 15,469,787 shares, \$0.01 par value per share.

Total No. of Pages 28

ACCESS PHARMACEUTICALS, INC.

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## PART I -- FINANCIAL INFORMATION

### Risk Factors

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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 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 integration of acquired companies and technologies, 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, the Annual Report on Form 10-K as of December 31, 2003, 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 our plan to complete full scale production of and to re-launch Aphthasol(R) in the third quarter of 2004, our planned start of a Phase III trial for our mucoadhesive liquid technology in the third quarter of 2004, and our net cash burn rate for the next twelve months to be approximately \$400,000 per month.

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

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We have recorded minimal revenue to date and we have incurred a cumulative operating loss of approximately \$59.1 million through June 30, 2004. Losses for the years ended 2003, 2002 and 2001 were \$6,935,000, \$9,384,000 and \$6,027,000, respectively. Our losses have resulted principally from costs incurred in research

and development activities related to our efforts to develop clinical candidates and from the associated administrative costs. We expect to incur additional operating losses over the next several years. We also expect cumulative losses to increase due to expanded research and development efforts and preclinical and clinical trials. Our net cash burn rate for the first six months of 2004 was \$700,000 per month. We project our net cash burn rate for the next twelve months to be approximately \$400,000 per month. Capital expenditures are forecasted to be minor for the next twelve months since most of our new equipment is leased and the lease expense is included in the calculation of the net cash burn rate.

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

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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 or Zindaclin(R) 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

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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.

We may not successfully commercialize our drug candidates.

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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 because:

- \* 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.

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

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

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We require substantial capital for our development programs and operating expenses, to pursue regulatory clearances and to prosecute and defend our intellectual property rights. Although we believe that our existing capital resources, interest income, product sales, royalties and revenue from possible licensing agreements and collaborative agreements will be sufficient to fund our currently expected operating expenses and capital requirements through 2005, we may need to raise substantial additional capital during that period to support our ongoing operations because our actual cash requirements may vary materially from those now planned and will depend upon numerous factors, including :

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

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 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.

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Our strategy for the research, development and commercialization of our potential pharmaceutical products may require us to enter into various arrangements with corporate and academic

collaborators, licensors, licensees and others, in addition to our existing relationships with other parties. Specifically, if we successfully develop any commercially marketable pharmaceutical products, we may seek to 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:

- \* amlexanox 5% paste
  - o Strakan Ltd. - United Kingdom and Ireland manufacturing and marketing rights
  - o Zambon Group - France, Germany, Holland, Belgium, Luxembourg, Switzerland, Brazil, Colombia and Italy manufacturing and marketing rights
  - o Laboratories Dr. Esteve SA - Spain, Portugal and Greece manufacturing and marketing rights
  - o Meda, AB for Scandinavia, the Baltic states and Iceland marketing rights
  - o Mipharm SpA for Italy manufacturing and marketing rights
  - o Paladin Labs, Inc. for Canada manufacturing and marketing rights

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- \* Zindaclin(R) and Residerm(R)
  - o Strakan Ltd. - worldwide manufacturing and marketing rights
  - o Fujisawa GmbH - sublicensed continental Europe marketing rights
  - o Taro - sublicensed Israel marketing rights
  - o Pliva dd Hrvatska - sublicensed Croatia marketing rights
  - o Various companies for 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 for sales of the product in North America. If this product is marketed, we will be dependent upon Wyeth 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.

Our strategy with respect to our other OraDisc(TM) products 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 other OraDisc(TM) products, to date we have not entered into any licensing arrangement. We may be unable to execute our licensing strategy for our other OraDisc(TM) products.

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.

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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 submission of products for regulatory approval and initiation of new development programs, which could cause our business to suffer. Delays or difficulties in establishing relationships with manufacturers to produce, package, label and distribute our finished pharmaceutical or other medical products, if any, market introduction and subsequent sales of such products could cause our business to suffer. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by the FDA. In

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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 after the manufacturing facility passes a pre-approval plant inspection. If we are unable to obtain or retain third party manufacturing on commercially acceptable terms, we may not be able to commercialize our products as planned. Our potential dependence upon third parties for the manufacture of our products may adversely affect our 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). Block Drug Company had manufactured the 5% amlexanox paste since the product was approved by the FDA in 1996 in a Puerto Rico facility certified by the FDA for Good Manufacturing Practices. We acquired the rights to amlexanox 5% paste from Block Drug Company on July 22, 2002. Also when we acquired the US rights to Aphthasol(R) we entered into a Supply Agreement whereby Block Drug Company was to produce Aphthasol(R) for us for a defined period of time at its Puerto Rico facility. We were subsequently advised by Block Drug Company that it was unable to comply with the terms of the Supply Agreement and that it would not be able to produce Aphthasol(R) for us. Due to Block Drug Company's production failure, we had sufficient product to supply wholesalers only through June 2003. We do not anticipate further sales of the product until the third quarter of 2004. We have selected Contract Pharmaceuticals Ltd. Canada as our new manufacturer of amlexanox 5% paste and it has produced initial qualifying batches of the product approved for manufacture in the US and Europe. Full scale production commenced in the first quarter of 2004.

Amlexanox 5% paste was approved by regulatory authorities for sale in the UK and is currently in the approval process in the remaining EU countries. We licensed manufacturing rights to Strakan, 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 Strakan Ltd. for the period of the patents. We receive a share of the licensing revenues and royalty on the sales of the product. Strakan has a contract manufacturer for Zindaclin(R) in

a European Union approved facility. Zindaclin(R) was approved in the UK and seven additional European Union countries and is currently under review for approval in the remaining EU countries.

OraDisc(TM) A was manufactured by a third party for our Phase III clinical trials. Enough product was manufactured to cover the needs of the clinical trials and testing. We have finalized with a third party a contract for manufacturing our product if our OraDisc(TM) A gains regulatory approval.

AP5280 and AP5346 are manufactured by a 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.

Our mucoadhesive technology is manufactured by a third party for our clinical trials.

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

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The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish their safety and efficacy. All of our drug candidates require governmental approvals for commercialization. Preclinical and clinical trials and manufacturing of our drug candidates will be subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product. The status of our principal products is as follows:

- \* 5% amlexanox paste is an approved product for sale in the US (Aphthasol(R)); approved in the UK and Canada but not yet sold; and, in the approval process in the EU.
- \* Zindaclin(R) is an approved product for sale in the UK and seven additional European Union countries; in the approval process in the remaining EU countries and other markets.
- \* OraDisc(TM) A has completed a Phase III clinical trial in the US and we filed an NDA in December 2003 with the FDA.
- \* Our other OraDisc(TM) products are currently in the pre-clinical phase.
- \* AP5280 has completed Phase I of its Phase I/II trial in Europe.
- \* AP5346 is currently in a Phase I trial in Europe.
- \* Mucoadhesive liquid technology is planned to start a clinical trial in the US in the third quarter of 2004.
- \* 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 you when we, independently or with our collaborative partners, might submit a New Drug Application, or "NDA", for FDA or other regulatory review.

Government regulation also affects the manufacturing and marketing of pharmaceutical products. Government regulations may delay marketing of our potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval could adversely affect our marketing as well as our ability to generate significant revenues from commercial sales. 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, Access, 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

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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.

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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. Companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials. In particular, OraDisc(TM) and AP5280 have taken longer to progress through clinical trials than originally planned. This extra time has not been related to concerns of the formulations but rather due to the lengthy regulatory process. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate. A delay or failure to receive regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in our attempts to further develop such candidates and obtain future regulatory approval.

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

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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.

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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

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any such liability could exceed our resources.

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

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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 platinum (AP5280) and DACH platinum (AP5346):

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

The following companies are working on therapies and formulations that may be competitive with our polymer platinum (AP5280) and DACH platinum (AP5346):

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

The following products may compete with our Residerm(R) products:

- \* Benzamycin, marketed by a subsidiary of Aventis;
- \* Cleocin-T and a generic topical clindamycin, marketed by Pharmacia;
- \* Benzac, marketed by a subsidiary of L'Oreal; and
- \* Triaz, marketed by Medicis Pharmaceutical Corp.

Technology and prescription steroids such as Kenalog in OraBase, developed by Bristol-Myers Squibb, may compete with our commercialized Aphthasol(R) product. 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 are Bristol-Myers-Squibb, Centocor (acquired by Johnson & Johnson), GlaxoSmithKline, Imclone and Xoma which are developing targeted monoclonal antibody therapy.

Aesgen, Amgen, CuraGen, RxKinetics and Sinclair are developing products to treat mucositis that may compete with our mucoadhesive liquid technology.

Emisphere Technologies, Inc., Biovail Corporation, CIMA Labs, Inc., Depomed Inc. and Flamel Technologies are developing products which compete with our oral drug delivery system.

Many of these competitors have and employ greater financial and other resources, including

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larger research and development staffs and more effective marketing and manufacturing organizations, than us or our collaborative partners. As a result, our competitors may successfully develop technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

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

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

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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 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.  
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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 and we intend to re-launch it in the third quarter of 2004. The product has been approved in the UK and Canada but has not been launched in any markets other than the United States.

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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.

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

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

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

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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 of technology to 26 U.S. patents and to 17 U.S. patent applications now pending, and 9 European patents and 15 European patent applications, we cannot assure you 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 2004 and 2019

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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 you that we will be able to obtain such licenses on acceptable terms, if at all. If we become involved in litigation regarding our intellectual property rights or the intellectual property rights of others, the potential cost of such litigation, regardless of the strength of our legal position, and the potential damages that we could be required to pay could be substantial.

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

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We are highly dependent upon the efforts of our senior management and scientific team, including our President and Chief Executive Officer, Kerry Gray. The loss of the services of one or more of these individuals could delay or prevent the achievement of our research, development, marketing, or product commercialization objectives. While we have employment agreements with Mr. Gray and David Nowotnik, PhD our Senior Vice President Research and Development, their employment may be terminated by them or us at any time. Mr. Gray's and Dr. Nowotnik's agreements expire within one year and are extendable each year on the anniversary date. We do not have employment contracts with our other key personnel. We do not maintain any "key-man" insurance policies on any of our key employees and we do not intend to obtain such insurance. In addition, due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific and technical personnel. In view of the stage of our development and our research and development programs, we have restricted our hiring to research scientists and a small administrative staff and we have made only limited investments in manufacturing, production, marketing, product sales or regulatory compliance resources. If we develop pharmaceutical products that we will commercialize ourselves, however, we will need to hire additional personnel skilled in the clinical testing and regulatory compliance process and in marketing and product sales. There is intense competition among major pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions for qualified personnel in the areas of our activities, however, and we may be unsuccessful in attracting and retaining these personnel.

Ownership of our shares is concentrated, to some extent, in the hands of a few investors which could limit the ability of our other stockholders to influence the direction of the company.

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Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.) and Heartland Advisors, Inc. each beneficially owned approximately 12.1% and 11.7%, respectively, of our common stock as of August 13, 2004.

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.

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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 our 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.

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The market price for our common stock could drop as a result of sales of a large number of our presently outstanding shares. All of the 15,469,787 shares of our common stock that are outstanding as of August 13, 2004, are unrestricted and freely tradable or tradable pursuant to a resale registration statement or under Rule 144 of the Securities Act.

#### 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 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 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, our Annual Report on Form 10-K as of December 31, 2003 and documents incorporated by reference and other documents 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 our plan to complete full scale production of and to re-launch Aphthasol(R) in the United States in the third quarter of 2004, our planned start of a Phase III trial in the United States for our mucoadhesive liquid technology and our net cash burn rate for the next twelve months to be approximately \$400,000 per month.

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## 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 eight drug delivery technology platforms:

- \* synthetic polymer targeted delivery,
- \* vitamin mediated targeted delivery,
- \* vitamin mediated oral delivery,
- \* bioerodible hydrogel technology,
- \* erodible mucoadhesive oral film technology,
- \* hydrogel particle aggregate technology,
- \* Residerm(R) topical delivery and
- \* carbohydrate targeting technology.

In addition, we plan to re-introduce Aphthasol(R) into United States market, which is 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.

Also, Strakan Limited, our United Kingdom partner, uses our patented Residerm(R) technology to produce and sell zinc clindamycin for the treatment of acne. Strakan began marketing zinc clindamycin in the United Kingdom under the trade name Zindaclin(R) in March 2002. The process to achieve marketing authorization for Zindaclin(R) throughout Europe has been initiated, with approvals in eight European Union countries to date and activities ongoing to expand approval throughout the European Union.

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 you 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, 2004, our accumulated deficit was \$59,134,000, of which \$8,894,000 was the result of the write-off of excess purchase price.

## 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, 2004 our cash and cash equivalents were \$7,117,000 and our working capital was \$5,753,000. Our working capital at June 30, 2004 represented an increase of \$4,547,000 as compared to our working capital as of December 31, 2003 of \$1,206,000. The increase in working capital was due to a private placement of common stock and warrants raising \$9.1 million of net proceeds offset by the loss from operations for the six months ended June 30, 2004.

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, 2004 of \$59,134,000. We expect that our existing capital resources will be adequate to fund our current level of operations through the end of 2005 excluding debt service. We cannot assure you that we will ever be able to generate significant product revenue or achieve or sustain profitability.

We will 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 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.

We have issued an aggregate of \$13,530,000 of convertible notes, which are due in two parts - \$8,030,000 is due on September 13, 2005 and \$5,500,000 is due on September 13, 2007. 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 dates described herein. We currently do not have the funds available to repay the convertible notes. We may need to restructure the terms of the notes as we near the due date for repayment. Any such restructuring could have a significant impact on our capital structure and liquidity.

#### SECOND QUARTER 2004 COMPARED TO SECOND QUARTER 2003

Our licensing revenue in the second quarter of 2004 was \$44,000, as compared to licensing revenue of \$447,000 in same quarter of 2003, a decrease of \$403,000 due to one time initial licensing fees received in 2003. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2004 and 2003 was from several agreements, including agreements related to various amlexanox projects and Residerm(R).

There were no product sales of Aphthasol(R) in the second quarter of 2004 due to a supply interruption, as compared to \$229,000 in sales in the second quarter of 2003. Currently, new supplies are

in the manufacturing process and sales are expected to commence in the third quarter of 2004.

Royalty income in the second quarter of 2004 was \$24,000, as compared to \$7,000 in the first quarter of 2003, and increase of \$17,000.

Total research spending for the second quarter of 2004 was \$1,281,000, as compared to \$1,497,000 for the same period in 2003, a decrease of \$216,000. The decrease in expenses was primarily the result of lower clinical costs (\$277,000) for our OraDisc(TM) clinical trial which was completed in 2003 and is currently under FDA review and (\$83,000) for the AP5280 and AP5346 polymer platinate clinical trials of which the AP5280 trial was completed in 2003 and of which the AP5346 trial is still ongoing.

The decrease in expenses was partially offset by:

- \* higher production and testing costs for Aphthasol(R) which is currently in production (\$86,000); and

- \* higher expenses at our Australian laboratory (\$44,000); and

- \* other net decreases (\$14,000).

Our cost of product sales was \$31,000 in the second quarter of 2004, as compared to \$104,000 in the second quarter of 2003, a decrease of \$73,000. The decrease in cost of product sales was due to the amlexanox supply interruption.

Total general and administrative expenses were \$772,000 for the second quarter of 2004, an increase of \$142,000 as compared to the same period in 2003. The increase in spending was due primarily to the following:

- \* higher preprofessional expenses (\$169,000) principally due to increased legal fees associated with compliance with the Sarbanes-Oxley Act, new contracts and legal proceedings;

- \* higher business consulting expenses for new business development activities (\$32,000);

- \* offset by lower patent expenses (\$51,000); and

- \* other net decreases (\$8,000).

Depreciation and amortization was \$160,000 for the second quarter of 2004 as compared to \$146,000 for the same period in 2003 reflecting an increase of \$14,000. 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 2004 were \$2,244,000 as compared to total operating expenses of \$2,377,000 for the same period in 2003, a decrease of \$133,000.

Loss from operations in the second quarter of 2004 was \$2,176,000 as compared to a loss of \$1,694,000 for the same period in 2003, an increased loss of \$482,000.

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Interest and miscellaneous income was \$35,000 for the second quarter of 2004 as compared to \$2,334,000 for the same period in 2003, a decrease of \$2,299,000. The decrease in miscellaneous income (\$2,280,000) was due to a one time settlement agreement with Block Drug Company in 2003. The decrease in interest income was due to lower interest rates in 2004 as compared with 2003.

Interest and other expense was \$412,000 for the second quarter of 2004 as compared to \$324,000 for the same period in 2004, an increase of \$88,000 due principally to the write-down of an investment in a publically traded stock associated with a product development agreement.



Net loss in the second quarter of 2004 was \$2,553,000, or a \$0.17 basic and diluted loss per common share, compared with net income of \$316,000, or a \$0.02 basic and diluted income per common share for the same period in 2003, a decrease of \$2,869,000.

#### SIX MONTHS ENDED JUNE 30, 2004 COMPARED TO SIX MONTHS ENDED JUNE 30, 2003

Our licensing revenue in the first six months of 2004 was \$48,000, as compared to licensing revenue of \$533,000 in the same period of 2003, a decrease of \$485,000 due to one time initial licensing fees received in 2003. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2004 and 2003 was from several agreements including agreements related to various amlexanox projects and ResiDerm(R).

There were no product sales of Aphthasol(R) in the first six months of 2004 due to a supply interruption, as compared to \$532,000 in sales in the same period of 2003. Currently, new supplies are in the manufacturing process.

Royalty income for the first six months of 2004 was \$40,000, as compared to \$11,000 in the same period of 2003, an increase of \$29,000.

Total research spending for the first six months of 2004 was \$2,425,000, as compared to \$3,294,000 for the same period in 2003, a decrease of \$869,000. The decrease in expenses was the result of:

- \* lower clinical costs for our OraDisc(TM) A clinical trial (\$698,000) which was completed in 2003 and is currently under FDA review and (\$472,000) for the AP5280 and AP5346 polymer platinate clinical trials of which the AP5280 trial was completed in 2003 and of which the AP5346 trial is still ongoing; and

- \* other net decreases (\$87,000).

The decrease in expenses was partially offset by:

- \* higher product development costs (\$163,000) for products made for our clinical trials and product testing;

- \* higher scientific salary costs (\$114,000) principally due to the hiring of additional employees; and

- \* higher expenses associated with our Australian laboratory (\$111,000).

Our cost of product sales was \$57,000 for the first six months of 2004, as compared to \$213,000 in

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the same period of 2003, a decrease of \$156,000. The decrease in cost of product sales was due to the amlexanox supply interruption.

Total general and administrative expenses were \$1,526,000 for the first six months of 2004, an increase of \$359,000 as compared to the same period in 2003. The increase in general and administrative expenses was due primarily to the following:

- \* higher professional expenses (\$271,000) principally due to increased legal fees associated with compliance with the Sarbanes-Oxley Act, new contracts and legal proceedings;

- \* higher business consulting expenses for new business development activities (\$61,000);

- \* higher patent expenses (\$12,000); and

- \* other net increases (\$15,000).

Depreciation and amortization was \$320,000 for the first six months of 2004 as compared to \$290,000 for the same period in

2003 reflecting an increase of \$30,000. 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 2004 were \$4,328,000 as compared to total operating expenses of \$4,964,000 for the same period in 2003, a decrease of \$636,000.

Loss from operations in the first six months of 2004 was \$4,240,000 as compared to a loss of \$3,888,000 for the same period in 2003, an increase of \$352,000.

Interest and miscellaneous income was \$68,000 for the first six months of 2004 as compared to \$2,432,000 for the same period in 2003, a decrease of \$2,500,000. The decrease in miscellaneous income was due to a one-time settlement agreement with Block Drug Company in 2003. The decrease in interest income was due to lower interest rates in 2004 as compared with 2003.

Interest and other expense was \$732,000 for the first six months of 2004 as compared to \$639,000 for the same period in 2003, an increase of \$93,000 due principally to the write-down of an investment in a publicly traded stock associated with a product development agreement.

Net loss in the first six months of 2004 was \$4,904,000, or a \$0.33 basic and diluted loss per common share, compared with a loss of \$2,095,000, or a \$0.16 basic and diluted loss per common share for the same period in 2003, a decrease of \$2,809,000.

### 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 2004 and 2005 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 \$39,000. The estimated effect assumes no changes in our short-term investments at June 30,

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2004. We do not believe that we are exposed to any other market risks, as defined. 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: We maintain disclosure controls and procedures designed to ensure that we are able to collect the information that we are required to disclose in the reports we file with the Securities and Exchange Commission, or the SEC, and to process, summarize and disclose this information within the time periods specified in the rules of the SEC. Based on their evaluation of our disclosure controls and procedures (defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of June 30, 2004, our Chief Executive and Chief Financial Officers have concluded that such disclosure controls and procedures are effective to ensure that information required to be disclosed in our periodic reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and regulations.

Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any within the Company have been detected. These inherent limitations include the

realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. While we believe that our disclosure controls and procedures are effective to provide a reasonable assurance of reaching our desired disclosure controls objective, because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

(b) Changes In Internal Controls: No changes in our internal controls over financial reporting occurred during the quarter ended June 30, 2004 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

## PART II -- OTHER INFORMATION

### ITEM 1 LEGAL PROCEEDINGS

William Hall ("Hall") filed suit against Access, and certain officers of Access, in Dallas County, Texas, District Court, on or about February 7, 2003. Although the claims in Hall's complaint were not clearly delineated, he appeared to bring claims for fraud, conspiracy, and theft against all defendants, and a claim for breach of contract against Access. Each of the allegations related to an allegedly unfulfilled contractual obligation to deliver to Hall 45,000 warrants to purchase our stock. Hall alleged in his complaint and in a subsequent letter that the warrants, had they been delivered, could have been worth as much as \$540,000. He sought as damages this amount, his attorney's fees, and an unstated amount of punitive damages.

We answered Hall's complaint on March 3, 2003, and brought counterclaims against him relating to certain alleged misrepresentations, his failure to perform certain obligations to Access, and his

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interference with the our right to enjoy certain contractual benefits. All claims were dismissed with prejudice on June 22, 2004.

Mipharm S.p.A. ("Mipharm") filed an arbitration against Access in the International Court of Arbitration of the International Chamber of Commerce (the "ICC") on or about October 23, 2003. Mipharm claims that we breached certain license agreements that existed between Mipharm and Access by failing to (1) make commercially reasonable efforts to obtain European Union regulatory approval for certain pharmaceutical products and (2) inform Mipharm of all significant news and actions relating to the approval process. Mipharm seeks damages of approximately \$350,000, and an order compelling us to perform pursuant to the license agreements.

We answered Mipharm's arbitration demand and simultaneously asserted counterclaims against Mipharm. In the counterclaims, we allege, inter alia, that Mipharm has itself breached the license agreements and that Mipharm is pursuing claims that it had previously agreed to release in exchange for valuable consideration. We believe that the claims in Mipharm's complaint are without merit and intend to be vigorous in both our defense of Mipharm's claims and in the pursuit of our counterclaims.

On January 16, 2004, Mipharm commenced a related lawsuit in Texas Federal Court, in which it alleged that one of Access's counterclaims should have been brought before a different

arbitral body. The Texas Court dismissed that action on April 20, 2004. On or about May 4, 2004, Mipharm filed a motion seeking reconsideration of the Court's decision or, alternatively, for leave to file an amended complaint, which we opposed. On or about July 23, 2004, the Texas court denied Mipharm's motion and upheld the dismissal of the Texas action. Mipharm has now filed a Notice of Appeal of the Texas Federal Court judgment. We believe that Mipharm's appeal would be frivolous and intend to be vigorous in our defense.

Del Pharmaceuticals, Inc. ("Del"), filed a complaint against Access on or about March 12, 2004, in the Court of Chancery in New Castle County, Delaware. The complaint purports to state claims for specific performance, breach of contract, unjust enrichment, promissory estoppel, breach of a duty of good faith, and misappropriation of trade secrets. Each of the allegations relates to allegedly unfulfilled or breached contractual obligations that Del claims arose from two confidentiality agreements and from negotiations related to a proposed license and supply agreement. The complaint seeks equitable relief and money damages. We filed a motion to dismiss all counts on several grounds on April 5, 2004. Del filed an opposition on June 14, 2004. On July 16, 2004, the court granted our motion to dismiss all of Del's claims and entered judgment in our favor.

On May 11, 2004, we filed a complaint against Del in the Supreme Court of the State of New York, County of Nassau, alleging breach of contract. Del counterclaimed on June 25, 2004, bringing the same claims that it had brought in the Delaware action. On August 6, the parties filed a stipulation of dismissal of all claims with the court.

#### ITEM 2 CHANGES IN SECURITIES

None

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#### 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 19, 2004 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:

\* Herbert H. McDade, Jr.; 11,486,182- For; and 353,537- Withheld Authority

\* Kerry P. Gray - 11,764,184- For; and 75,535- Withheld Authority

\* J. Michael Flinn; 11,764,183- For; and 75,536- Withheld Authority

The terms of office as a director of Access of each of Stuart M. Duty, Stephen B. Howell, Max Link, and John J. Meakem, Jr. continued after the meeting.

A proposal to ratify the appointment of Grant Thornton LLP as independent certified public accountants for the Company for the fiscal year ending December 31, 2004 was approved with 11,813,501- For; 10,513- Against; and 15,705- Abstain.

#### ITEM 5 OTHER INFORMATION

None

#### ITEM 6 EXHIBITS AND REPORTS ON FORM 8-K

Exhibits:

31.1 Certification of Chief Executive Officer of Access  
Pharmaceuticals, Inc. pursuant to Rule 13a-14(a)/15d-14(a)

31.2 Certification of Chief Financial Officer of Access  
Pharmaceuticals, Inc. pursuant to Rule 13a-14(a)/15d-14(a)

32.1\* Certification of Chief Executive Officer of Access  
Pharmaceuticals, Inc. pursuant to 18 U.S.C. Section 1350

32.2\* Certification of Chief Financial Officer of Access  
Pharmaceuticals, Inc. pursuant to 18 U.S.C. Section 1350

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\* This exhibit shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filings under the Securities Act of 1933 or the Securities and Exchange Act of 1934, whether made before or after the date hereof and irrespective of any general incorporation language

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in any filings.

Reports on Form 8-K:

On May 17, 2004, we filed a Current Report on Form 8-K (Item 9) furnishing a press release announcing our financial results for the first quarter ended March 31, 2004.

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SIGNATURES  
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Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACCESS PHARMACEUTICALS, INC.

Date: August 16, 2004  
-----

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

Kerry P. Gray  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: August 16, 2004  
-----

By: /s/ Stephen B. Thompson  
-----

Stephen B. Thompson  
Vice President and Chief Financial  
Officer  
(Principal Financial and Accounting  
Officer)

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Access Pharmaceuticals, Inc. and Subsidiaries  
Condensed Consolidated Balance Sheets

<TABLE>  
<CAPTION>

June 30, 2004    December 31, 2003  
-----

ASSETS	(unaudited)	
<S>	<C>	<C>
Current assets		
Cash and cash equivalents	\$ 6,148,000	\$ 727,000

Short term investments, at cost	969,000	1,860,000
Accounts receivable	1,128,000	1,149,000
Inventory	108,000	108,000
Prepaid expenses and other current assets	938,000	975,000
	-----	
Total current assets	9,291,000	4,819,000
Property and equipment, net	981,000	1,004,000
Debt issuance costs, net	221,000	313,000
Patents, net	2,484,000	2,652,000
Licenses, net	325,000	367,000
Goodwill, net	1,868,000	1,868,000
Other assets	630,000	788,000
	-----	
Total assets	\$15,800,000	\$11,811,000

#### LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

##### Current liabilities

Accounts payable and accrued expenses	\$ 1,194,000	\$ 1,780,000
Accrued interest payable	832,000	311,000
Deferred revenues	1,177,000	1,184,000
Current portion of note payable and other future obligations	335,000	338,000
	-----	
Total current liabilities	3,538,000	3,613,000

Long-term obligations for purchased patents - 158,000

Note payable, net of current portion 247,000 335,000

Convertible notes 13,530,000 13,530,000

Total liabilities 17,315,000 17,636,000

Commitments and contingencies - -

##### Stockholders' equity

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, 15,465,215 at June 30, 2004 and 13,397,034 at December 31, 2003	155,000	134,000
Additional paid-in capital	58,884,000	45,597,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Unamortized value of restricted stock grants	(370,000)	(294,000)
Treasury stock, at cost - 819 shares	(4,000)	(4,000)
Accumulated other comprehensive loss	(1,000)	14,000
Accumulated deficit	(59,134,000)	(54,227,000)
	-----	
Total stockholders' deficit	(1,515,000)	(5,825,000)

Total liabilities and stockholders'  
deficit \$15,800,000 \$11,811,000

</TABLE>

The accompanying notes are an integral part of these statements.

<TABLE>

<CAPTION>

	Three months ended		Six months ended	
	June 30,		June 30,	
	2004	2003	2004	2003
<S>	<C>	<C>	<C>	<C>
Revenues				
Licensing revenues	\$ 44,000	\$ 447,000	\$ 48,000	\$ 533,000
Product sales	-	229,000	-	532,000
Royalty income	24,000	7,000	40,000	11,000
Total revenues	68,000	683,000	88,000	1,076,000
Expenses				
Research and development	1,281,000	1,497,000	2,425,000	3,294,000
Cost of product sales	31,000	104,000	57,000	213,000
General and administrative	772,000	630,000	1,526,000	1,167,000
Depreciation and amortization	160,000	146,000	320,000	290,000
Total expenses	2,244,000	2,377,000	4,328,000	4,964,000
Loss from operations	(2,176,000)	(1,694,000)	(4,240,000)	(3,888,000)
Other income (expense)				
Interest and miscellaneous income	35,000	2,334,000	68,000	2,432,000
Interest and other expense	(412,000)	(324,000)	(732,000)	(639,000)
	(377,000)	2,010,000	(664,000)	1,793,000
Net income (loss)	\$(2,553,000)	\$316,000	\$(4,904,000)	\$(2,095,000)
Basic and diluted income (loss) per common share	\$(0.17)	\$0.02	\$(0.33)	\$(0.16)
Weighted average basic common shares outstanding	15,449,603	13,218,747	14,824,938	13,209,375
Weighted average diluted common shares outstanding	15,449,603	18,965,077	14,824,938	13,209,375
Net income (loss)	\$(2,553,000)	\$ 316,000	\$(4,904,000)	\$(2,095,000)
Other comprehensive income (loss)				
Foreign currency translation adjustment	(25,000)	8,000	(15,000)	3,000
Comprehensive income (loss)	\$(2,578,000)	\$324,000	\$(4,919,000)	\$(2,092,000)

</TABLE>

The accompanying notes are an integral part of these statements.

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Access Pharmaceuticals, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows  
(unaudited)

<TABLE>

<CAPTION>

	Six Months ended June 30,	
	2004	2003
<S>	<C>	<C>
Cash flows from operating activities:		

Net loss	\$ (4,904,000)	\$ (2,095,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Warrants issued in payment of consulting expenses	42,000	30,000
Amortization of restricted stock grants	60,000	45,000
Depreciation and amortization	320,000	291,000
Amortization of debt costs	92,000	92,000
Change in operating assets and liabilities:		
Accounts receivable	21,000	180,000
Accrued interest receivable	-	12,000
Inventory	-	256,000
Prepaid expenses and other current assets	37,000	261,000
Other assets	158,000	56,000
Accounts payable and accrued expenses	(586,000)	(916,000)
Accrued interest payable	521,000	521,000
Deferred revenues	(7,000)	(207,000)
	-----	-----
Net cash used in operating activities	(4,246,000)	(1,474,000)
	-----	-----
Cash flows from investing activities:		
Capital expenditures	(87,000)	(306,000)
Redemptions of short term investments and certificates of deposit	891,000	4,151,000
	-----	-----
Net cash provided by investing activities	804,000	3,845,000
	-----	-----
Cash flows from financing activities:		
Payments of notes payable and long-term obligations	(249,000)	(717,000)
Proceeds from stock issuances, net of costs of \$647,000	9,130,000	189,000
	-----	-----
Net cash provided by (used in) financing activities	8,881,000	(528,000)
	-----	-----
Net increase in cash and cash equivalents	5,439,000	1,843,000
Effect of exchange rate changes on cash	(18,000)	3,000
Cash and cash equivalents at beginning of period	727,000	1,444,000
	-----	-----
Cash and cash equivalents at end of period	\$ 6,148,000	\$ 3,290,000
	=====	=====
Cash paid for interest	\$15,000	\$18,000
Supplemental disclosure of noncash transactions		
Assets acquired from Block Drug settlement	-	244,000
Value of restricted stock grants	136,000	-

</TABLE>

The accompanying notes are an integral part of these statements.

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Access Pharmaceuticals, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements  
Six Months Ended June 30, 2004 and 2003  
(unaudited)

(1) Interim Financial Statements

The consolidated balance sheet as of June 30, 2004 and the consolidated statements of operations and cash flows for the three and six months ended June 30, 2004 and 2003 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, 2003. The results of operations for the period ended June 30, 2004 are not necessarily indicative of the operating results which may be expected for a full year. The consolidated balance sheet as of December 31, 2003 contains financial information taken from the audited financial statements as of that date.

## (2) Intangible Assets

Intangible assets consist of the following (in thousands):

	June 30, 2004		December 31, 2003	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
Amortizable intangible assets				
Patents	\$ 3,178	\$ 830	\$ 3,178	\$ 526
Licenses	830	505	830	463
Total	\$ 4,008	\$ 1,199	\$ 4,008	\$ 989

</TABLE>

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Amortization expense related to intangible assets totaled \$105,000 and \$106,000 for the three months ended June 30, 2004 and 2003, respectively and totaled \$210,000 and \$211,000 for the six months ended June 30, 2004 and 2003, respectively. The aggregate estimated amortization expense for intangible assets remaining as of June 30, 2004 is as follows (in thousands):

2004	\$ 211
2005	421
2006	421
2007	395
2008	370
Thereafter	991
Total	\$ 2,809

## (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,	
	2004	2003	2004	2003
Net income (loss) as reported	\$(2,553,000)	\$ 316,000	\$(4,904,000)	\$(2,095,000)
Deduct: Stock-based employee compensation expense determined under fair value based				

method	(129,000)	(309,000)	(299,000)	(604,000)
Pro forma	\$(2,682,000)	\$ 7,000	\$(5,203,000)	\$(2,699,000)

Basic and diluted income

(loss) per share:				
As reported	\$(0.17)	\$0.02	\$(0.33)	\$(0.16)
Pro forma	(0.17)	0.00	(0.35)	(0.20)

</TABLE>

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

<TABLE>

<CAPTION>

Three months ended June 30, Six Months ended June 30,

	2004	2003	2004	2003
<S>	<C>	<C>	<C>	<C>
Fully diluted shares	20,756,672	18,007,411	20,,132,027	17,998,039

</TABLE>

CERTIFICATION

I, Kerry P. Gray, the President and 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)) 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. 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

c. 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 16, 2004

/s/ Kerry P. Gray

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Kerry P. Gray  
President and 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)) 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. 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

c. 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 16, 2004

/s/ Stephen B. Thompson

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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, 2004, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Kerry P. Gray, President and 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 (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 16th day of August, 2004.

/s/ Kerry P. Gray

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Kerry P. Gray  
President and 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, 2004, 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 (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 16th day of August, 2004.

/s/ Stephen B. Thompson

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Stephen B. Thompson  
Chief Financial Officer