

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 MARCH 31, 2004

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 May 14, 2004, was 15,465,215 shares, \$0.01 par value per share.

Total No. of Pages 25

ACCESS PHARMACEUTICALS, INC.

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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 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 Aphthasol(R) in the second quarter of 2004, re-start sales of Aphthasol(R) in the second quarter of 2004, mucoadhesive liquid technology planned start of a Phase III trial in the US in the third quarter of 2004, and 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.

We have recorded minimal revenue to date and we have incurred a cumulative operating loss of approximately \$56.6 million through March 31, 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 three months of 2004 was \$849,000 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.

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

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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.

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 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.

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

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

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

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numerous factors, including :

- * the sales levels of our currently 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.

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

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- o Paladin Labs, Inc. for Canada manufacturing and marketing rights

- * 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

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 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 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 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. At such time when

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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 second quarter of 2004. We acquired the rights to amlexanox 5% paste from Block Drug Company on July 22, 2002. 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 a UK filing has been made to approve this facility for European supply.

We licensed our patents for worldwide manufacturing and marketing for Zindaclin(R) and the 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) 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 finalized with a third party a contract for manufacturing our product if our product 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.

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

The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish their safety and efficacy. All of our drug candidates 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:

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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; 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) has completed a Phase III clinical trial in the US and we filed an NDA.
- * AP5280 has completed Phase I of its Phase I/II trial in Europe and we are analyzing the results to start the Phase II part of the trial.
- * AP5346 is currently in a Phase I trial in Europe.
- * Mucoadhesive liquid technology is planned to start a Phase III 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 and 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. 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

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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.

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 platinum (AP5280) and DACH platinum (AP5346):

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

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* 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

* Cell Therapeutics, Daiichi, Enzon and Inhale are developing alternate drugs in combination with polymers.

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.

Amgen, CuraGen, Sinclair and RxKinetics 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 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.

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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 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 is not widely accepted in the marketplace and its 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 second 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.

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

Lower prices for pharmaceutical products may result from:

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

The cost containment measures that healthcare providers are instituting, including practice protocols and guidelines and clinical pathways, and the effect of any healthcare reform, could

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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 of technology to 26 U.S. patents and to 16 U.S. patent applications now pending, and 7 European patents and 17 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

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.

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,

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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 no investment in manufacturing, production, marketing, product sales or regulatory compliance resources. If we develop pharmaceutical products that we will commercialize ourselves, however, we will need to hire additional personnel skilled in the clinical testing and regulatory compliance process and in marketing and product sales. There is intense competition among major pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions for qualified personnel in the areas of our activities, however, and we may be unsuccessful in attracting and retaining these personnel.

Ownership of our shares is concentrated, to some extent, in the hands of a few 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. each beneficially owned approximately 12.1% and 11.7%, respectively, of our common stock as of May 14, 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.

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.

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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. All of the 15,465,215 shares of our common stock that are outstanding as of May 14, 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 Aphthasol(R) in the second quarter of 2004.

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 are marketing Aphthasol(R) in the United States, which is the first FDA approved product for the treatment of canker sores. We are developing new formulations and delivery

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forms of amlexanox, including mucoadhesive disc delivery.

Also, Strakan Limited, our United Kingdom partner, has used our patented Residerm(R) technology to develop 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 March 31, 2004, our accumulated deficit was \$56,581,000, 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 March 31, 2004 our cash and cash equivalents were \$9,295,000 and our working capital was \$8,022,000. Our working capital at March 31, 2004 represented an increase of \$6,816,000 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 three months ended March 31, 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 March 31, 2004 of \$56,581,000. 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;

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- * 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 \$1,041,000 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 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.

FIRST QUARTER 2004 COMPARED TO FIRST QUARTER 2003

Our licensing revenue in the first quarter of 2004 was \$4,000, as compared to licensing revenue of \$86,000 in same quarter of 2003, a decrease of \$82,000. 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 quarter of 2004 due to a supply interruption, as compared to \$303,000 in sales in the first quarter of 2003. Currently, new supplies are in the manufacturing process.

Royalty income in the first quarter of 2004 was \$16,000, as compared to \$4,000 in the first quarter of 2003.

Total research spending for the first quarter of 2004 was \$1,144,000, as compared to \$1,797,000 for the same period in 2003, a decrease of \$653,000. The decrease in expenses was primarily the result of:

- * lower clinical costs (\$417,000) for our OraDisc(TM) clinical trial which was completed in 2003 and is currently under FDA review and (\$314,000) for the AP5280 and AP5346 polymer platinate clinical trials of which the AP5280 trial

was competed in 2003 and the AP5346 trial is still ongoing; and

* other net decreases (\$66,000).

The decrease in expenses was partially offset by:

* higher production and testing costs for Aphthasol(R) which is currently in production (\$77,000); and

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* higher expenses at our Australian laboratory (\$67,000).

Our cost of product sales was \$26,000 in the first quarter of 2004, as compared to \$109,000 in the first quarter of 2003, a decrease of \$83,000. The decrease in cost of product sales was due to the amlexanox supply interruption.

Total general and administrative expenses were \$754,000 for the first quarter of 2004, an increase of \$217,000 as compared to the same period in 2003. The increase in spending was due primarily to the following:

* higher investor relations expenses (\$72,000);

* higher patent expenses (\$62,000), due to new patent expenses;

* higher legal expenses (\$56,000) primarily due to increased legal fees associated with compliance with the Sarbanes-Oxley Act, new contracts and legal proceedings.

* higher salary and related costs (\$29,000); and

* offset by other net decreases (\$2,000).

Depreciation and amortization was \$160,000 for the first quarter of 2004 as compared to \$144,000 for the same period in 2003 reflecting an increase of \$16,000. The increase in depreciation and amortization was due to increased depreciation resulting from the acquisition of additional capital assets.

Total operating expenses in the first quarter of 2004 were \$2,084,000 as compared to total operating expenses of \$2,587,000 for the same period in 2003, a decrease of \$503,000.

Loss from operations in the first quarter of 2004 was \$2,064,000 as compared to a loss of \$2,194,000 for the same period in 2003, a decrease of \$130,000.

Interest and miscellaneous income was \$33,000 for the first quarter of 2004 as compared to \$98,000 for the same period in 2003, a decrease of \$65,000. The decrease in interest income was due to lower cash balances and lower interest rates in 2004 as compared with 2003.

Interest expense was \$320,000 for the first quarter of 2004 as compared to \$315,000 for the same period in 2004, an increase of \$5,000.

Net loss in the first quarter of 2004 was \$2,351,000, or a \$0.15 basic and diluted loss per common share, compared with a loss of \$2,411,000, or a \$0.18 basic and diluted loss per common share for the same period in 2003, a decrease of \$60,000.

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

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\$23,000. The estimated effect assumes no changes in our short-term investments at March 31, 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 March 31, 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. 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 March 31, 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 are not clearly delineated, he appears to bring claims for fraud, conspiracy, and theft against all defendants, and a claim for breach of contract against Access. Each of the allegations relates to an allegedly unfulfilled contractual obligation to deliver to Hall 45,000 warrants to purchase our stock. Hall alleges 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 seeks 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,

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and his interference with our right to enjoy certain contractual benefits. Discovery, substantive fact investigation, and legal analysis have not been completed. We intend to be vigorous in both our defense of Hall's claims and in the pursuit of our counterclaims.

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 have 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 seek approximately \$2.2 million in damages. 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 alleges that one of Access's counterclaims should have been brought before a different arbitral body. That 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. We are opposing that motion.

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.

The complaint has only recently been served, and we have filed a motion to dismiss all counts on several grounds. That motion to dismiss is currently pending. Discovery, substantive fact investigation, and detailed legal analysis have only just begun. We believe that the allegations in the complaint are without merit and intend to be vigorous in both our defense of Del's claims and in the pursuit of contemplated counterclaims.

ITEM 2 CHANGES IN SECURITIES

On February 24, 2004, we completed the closing of a private offering to individual accredited investors, at a per share price of \$5.40, receiving gross proceeds of \$9.7 million from the private placement of 1,789,371 shares of common stock. The investors also received five 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. The shares and common stock underlying the warrants issued in this private placement were registered for resale on March 24, 2004. We relied on Section 4(2) and/or 3(b) of the 1933 Securities Act and the provisions of Regulation D as

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exemptions from the registration thereunder. The proceeds of the offering will be used principally for general corporate purposes and to fund the development of our portfolio of product candidates.

ITEM 3 DEFAULTS UPON SENIOR SECURITIES

None

ITEM 4 SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

None

ITEM 5 OTHER INFORMATION

None

ITEM 6 EXHIBITS AND REPORTS ON FORM 8-K

Exhibits:

10.26 License and Supply Agreement between Wyeth, acting through its Wyeth Consumer Healthcare Division and us dated January 6, 2004. (Confidential Treatment requested)

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

* 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 in any filings.

Reports on Form 8-K:

On March 25, 2004, we filed a Current Report on Form 8-K (Items 7 and 12) furnishing a press release announcing our financial results for the fourth quarter and the year ended December 31, 2003.

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SIGNATURES

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: May 17, 2004 By: /s/ Kerry P. Gray
----- -----
Kerry P. Gray
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 17, 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>

| | March 31, 2004 | December 31, 2003 |
|---------------------------------|----------------|-------------------|
| | ----- | ----- |
| ASSETS | (unaudited) | |
| <S> | <C> | <C> |
| Current assets | | |
| Cash and cash equivalents | \$ 8,356,000 | \$ 727,000 |
| Short term investments, at cost | 939,000 | 1,860,000 |
| Accounts receivable | 1,189,000 | 1,149,000 |

| | | |
|---|---------------|---------------|
| Inventory | 108,000 | 108,000 |
| Prepaid expenses and other current assets | 1,088,000 | 975,000 |
| | ----- | ----- |
| Total current assets | 11,680,000 | 4,819,000 |
| Property and equipment, net | 1,009,000 | 1,004,000 |
| Debt issuance costs, net | 267,000 | 313,000 |
| Patents, net | 2,568,000 | 2,652,000 |
| Licenses, net | 346,000 | 367,000 |
| Goodwill, net | 1,868,000 | 1,868,000 |
| Other assets | 758,000 | 788,000 |
| | ----- | ----- |
| Total assets | \$ 18,496,000 | \$ 11,811,000 |
| | ===== | ===== |

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)

Current liabilities

| | | |
|--|--------------|--------------|
| Accounts payable and accrued expenses | \$ 1,655,000 | \$ 1,780,000 |
| Accrued interest payable | 572,000 | 311,000 |
| Deferred revenues | 1,180,000 | 1,184,000 |
| Current portion of note payable and other future obligations | 251,000 | 338,000 |
| | ----- | ----- |
| Total current liabilities | 3,658,000 | 3,613,000 |

Long-term obligations for purchased patents - 158,000

Note payable, net of current portion 355,000 335,000

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

Total liabilities 17,543,000 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, 15,382,918 at March 31, 2004 and 13,397,034 at December 31, 2003 | 154,000 | 134,000 |
| Additional paid-in capital | 58,806,000 | 49,597,000 |
| Notes receivable from stockholders | (1,045,000) | (1,045,000) |
| Unamortized value of restricted stock grants | (401,000) | (294,000) |
| Treasury stock, at cost - 819 shares | (4,000) | (4,000) |
| Accumulated other comprehensive loss | 24,000 | 14,000 |
| Accumulated deficit | (56,581,000) | (54,227,000) |
| | ----- | ----- |

Total stockholders' equity (deficit) 953,000 (5,825,000)

Total liabilities and stockholders' equity (deficit) \$18,496,000 \$11,811,000

</TABLE>

The accompanying notes are an integral part of these statements.

<TABLE>
<CAPTION>

| | Three Months ended March 31, | |
|--|------------------------------|----------------|
| | 2004 | 2003 |
| <S> | <C> | <C> |
| Revenues | | |
| Licensing revenues | \$ 4,000 | \$ 86,000 |
| Product sales | - | 303,000 |
| Royalty income | 16,000 | 4,000 |
| Total revenues | 20,000 | 393,000 |
| Expenses | | |
| Research and development | 1,144,000 | 1,797,000 |
| Costs of product sales | 26,000 | 109,000 |
| General and administrative | 754,000 | 537,000 |
| Depreciation and amortization | 160,000 | 144,000 |
| Total expenses | 2,084,000 | 2,587,000 |
| Loss from operations | (2,064,000) | (2,194,000) |
| Other income (expense) | | |
| Interest and miscellaneous income | 33,000 | 98,000 |
| Interest and debt expense | (320,000) | (315,000) |
| | (287,000) | (217,000) |
| Net loss | \$ (2,351,000) | \$ (2,411,000) |
| Basic and diluted loss per common share | \$ (0.17) | \$ (0.18) |
| Weighted average basic and diluted common shares outstanding | 14,200,273 | 13,199,900 |
| Net loss | \$ (2,351,000) | \$ (2,411,000) |
| Other comprehensive income (loss) | | |
| Foreign currency translation adjustment | 10,000 | (5,000) |
| Comprehensive loss | \$ (2,341,000) | \$ (2,416,000) |

</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>

| | Three Months ended March 31, | |
|---|------------------------------|----------------|
| | 2004 | 2003 |
| <S> | <C> | <C> |
| Cash flows from operating activities: | | |
| Net loss | \$ (2,351,000) | \$ (2,411,000) |
| 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 | 29,000 | 21,000 |
| Depreciation and amortization | 160,000 | 144,000 |
| Amortization of debt costs | 46,000 | 46,000 |
| Other long-term obligations | - | - |
| Change in operating assets and liabilities: | | |
| Accounts receivable | (40,000) | (236,000) |

| | | | |
|---|--------------|--------------|-------------|
| Inventory | - | 223,000 | |
| Prepaid expenses and other current assets | (113,000) | | 234,000 |
| Other assets | 30,000 | 28,000 | |
| Accounts payable and accrued expenses | (125,000) | | 15,000 |
| Accrued interest payable | 261,000 | 260,000 | |
| Deferred revenues | (4,000) | (203,000) | |
| | ----- | ----- | |
| Net cash used in operating activities | (2,065,000) | | (1,849,000) |
| | ----- | ----- | |
| Cash flows from investing activities: | | | |
| Capital expenditures | (60,000) | (95,000) | |
| Redemptions of short term investments and certificates of deposit | 921,000 | 4,179,000 | |
| | ----- | ----- | |
| Net cash provided by investing activities | 861,000 | | 4,084,000 |
| | ----- | ----- | |
| Cash flows from financing activities: | | | |
| Payments of notes payable and long-term obligations | (225,000) | (451,000) | |
| Proceeds from stock issuances, net of costs of \$647,000 | 9,035,000 | - | |
| | ----- | ----- | |
| Net cash provided by (used in) financing activities | 8,810,000 | (451,000) | |
| | ----- | ----- | |
| Net increase in cash and cash equivalents | 7,606,000 | 1,784,000 | |
| Effect of exchange rate changes on cash | 23,000 | (5,000) | |
| Cash and cash equivalents at beginning of period | 727,000 | 1,444,000 | |
| | ----- | ----- | |
| Cash and cash equivalents at end of period | \$ 8,356,000 | \$ 3,223,000 | |
| | ===== | ===== | |

| | | |
|------------------------|---------|---------|
| Cash paid for interest | \$6,000 | \$6,000 |
|------------------------|---------|---------|

</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
Three Months Ended March 31, 2004 and 2003
(unaudited)

(1) Interim Financial Statements

The consolidated balance sheet as of March 31, 2004 and the consolidated statements of operations and cash flows for the three months ended March 31, 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 March 31, 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):

<TABLE>
<CAPTION>

| | March 31, 2004 | | December 31, 2003 | |
|-------------------------------|----------------------|--------------------------|----------------------|--------------------------|
| | Gross carrying value | Accumulated amortization | Gross carrying value | Accumulated amortization |
| <S> | <C> | <C> | <C> | <C> |
| Amortizable intangible assets | | | | |
| Patents | \$ 3,178 | \$ 610 | \$ 3,178 | \$ 526 |
| Licenses | 830 | 484 | 830 | 463 |
| Total | \$ 4,008 | \$ 1,094 | \$ 4,008 | \$ 989 |

</TABLE>

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Amortization expense related to intangible assets totaled \$105,000 for each of the three months ended March 31, 2004 and 2003. The aggregate estimated amortization expense for intangible assets remaining as of March 31 is as follows (in thousands):

| | |
|------------|---------|
| 2004 | \$ 316 |
| 2005 | 421 |
| 2006 | 421 |
| 2007 | 395 |
| 2008 | 370 |
| Thereafter | 991 |
| Total | \$2,914 |

(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 March 31, | |
|--|------------------------------|---------------|
| | 2004 | 2003 |
| <S> | <C> | <C> |
| Net loss | | |
| As reported | \$(2,351,000) | \$(2,411,000) |
| Deduct: Stock-based employee compensation expense determined under fair value based method | (170,000) | (294,000) |
| Pro forma | \$(2,521,000) | \$(2,705,000) |
| Basic and diluted loss per share: | | |
| As reported | \$(0.17) | \$(0.18) |
| Pro forma | (0.18) | (0.20) |

</TABLE>

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

(4) Sales of Securities

On February 24, 2004, we completed the closing of a private offering to individual accredited investors, at a per share price of \$5.40, receiving gross proceeds of \$9.7 million from the private placement of 1,789,371 shares of common stock. The investors also received five 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. The shares and common stock underlying the warrants issued in this private placement were registered for resale on March 24, 2004. We relied on Section 4(2) and/or 3(b) of the 1933 Securities Act and the provisions of Regulation D as exemptions from the registration thereunder. The proceeds of the offering will be used principally for general corporate purposes and to fund the development of our portfolio of product candidates.

EXECUTION COPY

LICENSE AND SUPPLY AGREEMENT

dated as of January 6, 2004

between

WYETH

acting through its Wyeth Consumer Healthcare Division

and

ACCESS PHARMACEUTICALS, INC.

THIS LICENSE AND SUPPLY AGREEMENT (this "Agreement") is made and entered into as of this 6th day of January, 2004 (the "Effective Date"), between WYETH, a corporation organized and existing under the laws of Delaware, acting through its Wyeth Consumer Healthcare Division, and having an address at Five Giralda Farms, Madison, New Jersey 07940 ("WYETH") and Access Pharmaceuticals, Inc., a corporation organized and existing under the laws of Delaware and having an address at 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207-2107 ("ACCESS").

RECITALS

WHEREAS, ACCESS is developing a proprietary oral mucoadhesive, erodible form of drug that contains * as more fully described in Exhibit A attached hereto (the "Product"), * ;

WHEREAS, WYETH possesses substantial resources and expertise in the commercialization and marketing of over-the-counter pharmaceutical products; and

WHEREAS, ACCESS desires to grant to WYETH, and WYETH desires to obtain from ACCESS, an exclusive license to market the Product and an exclusive right to purchase from ACCESS and distribute the Product, all under the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and for good and valuable consideration the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. DEFINITIONS

1.1 Definitions.

As used in this Agreement, the following capitalized terms have the meanings indicated below:

1.1.1 "ACCESS" has the meaning set forth in the Preamble.

1.1.2 "ACCESS Confidential Information" means all information, specifications (including, without limitation, the Specifications), know-how and data pertaining to the Product and ACCESS's business or its Manufacturing operations disclosed to WYETH or its Affiliates, Third Party manufacturers or distributors hereunder, including, without limitation, all information, Specifications, know-how and data related to the design, implementation, performance and manufacture of the Product, and any correspondence with the FDA or any other Regulatory Authority, clinical study data, analytical data, or operating procedures.

* - Confidential portions have been omitted and are on file separately with the Commission.

1.1.3 "ACCESS Trademark" means any trademark, trade name, trade dress, slogan, logo, or similar item used by ACCESS prior to or as of the Effective Date, or subsequent to the Effective Date in connection with any ACCESS product other than the Product.

1.1.4 "Affiliate" means, in the case of either Party, any corporation, joint venture, or other business entity which directly or indirectly controls, is controlled by, or is under common control with that Party. The term "control," as used in this definition, means having the power to direct, or cause the direction of, the management and policies of an entity, whether through ownership of voting securities, by contract or otherwise. Notwithstanding the foregoing, for purposes of this Agreement, the term "Affiliate" does not include entities in which a Party or its Affiliates owns a majority of the ordinary voting power to elect a majority of the board of directors but is restricted from electing such majority by contract or otherwise, until such time as such restrictions are no longer in effect.

1.1.5 "Batch" means the volume of finished, packaged Product obtained from a validated Manufacturing run.

1.1.6 "Certificate of Analysis" means the document identifying the results of the Methods of Analysis for a specific Batch of Product in a form agreed to by the Parties in writing but which shall include, without limitation, the applicable Product Batch's manufacturing date, expiration date, lot number and testing results and data.

1.1.7 "Confidential Information" means either WYETH Confidential Information, ACCESS Confidential Information, or both, as the context requires.

1.1.8 "Contract Year" means each consecutive twelve (12) month period during the Term, the first of which shall commence on the first day of the calendar month following the date of Launch and end on the first anniversary thereof.

1.1.9 "Control" means, with respect to any item of information or intellectual property right, the possession, whether by ownership or exclusive license, of the right to grant a license or other right with respect thereto.

1.1.10 "Effective Date" has the meaning set forth in the Preamble.

1.1.11 "Extraordinary Event Increase" has the meaning set forth in Section 5.5.2.

1.1.12 "Facility" means ACCESS's initial Third Party Manufacturing facility, and any subsequent or replacement Third Party Manufacturing facility identified to and approved by WYETH in accordance with Section 2.9.

1.1.13 "FDA" means (a) the United States Food and Drug Administration, or (b) with respect to countries in the Territory other than the United States, any foreign regulatory agency or governmental entity which fulfills a role similar to the United States Food and Drug Administration, or any successor entities thereto.

1.1.14 "FD&C Act" means (a) the Federal Food, Drug and Cosmetic Act, and all regulations promulgated thereunder, or (b) with respect to countries in the Territory other than the United States, any foreign laws, statutes, rules or regulations fulfilling a role similar to the Federal Food, Drug and Cosmetic Act (and all regulations promulgated thereunder), as the same may be amended or supplemented from time to time.

1.1.15 "Field" means the treatment of oral pain utilizing anesthetics (excluding the treatment of sore throat and

excluding any product containing amlexanox as an active ingredient).

1.1.16 "Force Majeure Event" has the meaning set forth in Article 10.

1.1.17 "Good Manufacturing Practice" or "GMP" means (a) the then current standards for the manufacture of pharmaceuticals, as set forth in the FD&C Act, (b) such standards of good manufacturing practice as are required by the applicable laws and regulations of countries in which the Product is intended to be sold, to the extent such standards are not inconsistent with the then current standards for the manufacture of pharmaceuticals as set forth in the FD&C Act, and (c) any quality requirements set forth in this Agreement or the Quality Agreement attached hereto as Exhibit C.

1.1.18 "Indemnified Party" has the meaning set forth in Section 7.1.3.

1.1.19 "Indemnifying Party" has the meaning set forth in Section 7.1.3.

1.1.20 "Intellectual Property Rights" means Patents, designs, formulae, trade secrets, know-how, industrial models, and technical information Controlled by ACCESS and whether now existing or coming into existence during the Term and which are necessary for and/or related to the use or distribution of the Product.

1.1.21 "Invention" means any new or useful method, process, manufacture, compound or composition of matter, whether or not patentable or copyrightable, or any improvement thereof arising during the Term with respect to the Product, its Manufacture and/or use.

1.1.22 "Launch" means the date on which the Product is sold by WYETH for the first time to a Third Party for commercial distribution in the Territory.

1.1.23 "Manufacture," "Manufactured" or "Manufacturing" means all activities involved in the production of the Product, including, without limitation, the preparation, formulation, finishing, testing, packaging, storage and labeling of the Product and the handling, storage and disposal of any residues or wastes generated thereby.

1.1.24 "Mark" has the meaning set forth in Section 2.1.4.

1.1.25 "Materials" means all materials, including, without limitation, all raw

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materials, ingredients, packaging supplies and labels, required for the Manufacture of Product.

1.1.26 "Methods of Analysis" means the methods of analysis for the Product which are mutually agreed upon in writing between the Parties and, on a date to be mutually agreed upon by the Parties, attached as an exhibit to the development plan (which development plan shall be agreed upon in accordance with Section 2.10).

1.1.27 "Net Sales" means, with respect to the Product, the gross invoiced sales amount of the Product sold by WYETH or its Affiliates to non-affiliate Third Parties, after deduction of the following items, to the extent that such deductions are reasonable and actually allowed, taken or incurred, and (provided that such items do not exceed reasonable and customary amounts in the country in which the sale occurred): (a) trade and quantity discounts, net of any give-backs received by WYETH in return; (b) refunds, rebates, retroactive price adjustments, service allowances and broker's or agent's

commissions; (c) credits or allowances given for rejection or return of previously sold Product or for wastage replacement actually taken or allowed; and (d) any tax, duties or government charge levied on the sale of Product and borne by WYETH and/or its Affiliates (excluding national, state or local taxes based on income). Such amounts shall be determined from the books and records of WYETH and its Affiliates maintained in accordance with generally accepted accounting principles, consistently applied. Sales of the Product by and between a Party and its Affiliates for further distribution to a Third Party are not sales to Third Parties and shall be excluded from Net Sales calculations for all purposes.

1.1.28 "Party" or "Parties" means either WYETH, ACCESS or both, as the context requires.

1.1.29 "Patents" shall mean (a) * , and (b) any and all patents, patent applications, patent disclosures awaiting filing determination, patent divisionals, continuations, continuations-in-part, reissues, re-examinations, renewals and extensions thereof Controlled by ACCESS during the Term, within the Territory, which are necessary for the Manufacture, use or distribution of the Product.

1.1.30 "Person" means any natural person, corporation, general partnership, limited partnership, limited liability company, limited liability partnership proprietorship, other business organization, trust, union, association or governmental authority.

1.1.31 "PPI Adjustment" has the meaning set forth in Section 5.2.

1.1.32 "Product" has the meaning set forth in the first recital above.

* - Confidential portions have been omitted and are on file separately with the Commission.

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1.1.33 "Recall" means any action by any Party to recover title to or possession of any Product sold or shipped to Third Parties or any action to prevent or interrupt the sale or shipment by a Party of the Product to Third Parties that would have been subject to recall if it had been sold or shipped.

1.1.34 "Regulatory Approval" means all consents, permits, approvals, licenses, authorizations, qualifications, notices or orders that are issued or granted by Regulatory Authorities which are required for the manufacture, marketing, promotion, pricing and sale of the Product in a country within the Territory.

1.1.35 "Regulatory Authority" means any domestic or foreign, federal, national, regional, state, county, city, municipal, local or other administrative, legislative regulatory or other governmental authority, agency, department, bureau, commission, or council involved in the granting of Regulatory Approval for the Product in the Territory.

1.1.36 "Rolling Forecast" has the meaning set forth in Section 2.2.

1.1.37 "Seizure" means any action by the FDA or any other Regulatory Authority to detain or destroy the Product or prevent the release of the Product.

1.1.38 "Shortfall" has the meaning set forth in Section 2.6.

1.1.39 "Specifications" means the specifications for the Product which are mutually agreed upon in writing between the Parties and, on a date to be mutually agreed upon by the Parties, attached as an exhibit to the development plan (which

development plan shall be agreed upon in accordance with Section 2.10).

1.1.40 "Term" means, with respect to each country in the Territory, the period commencing on the Effective Date and ending upon the expiration of the last-to-expire patent within the Patents in such country, except as and if sooner terminated in accordance with Section 8.

1.1.41 "Territory" means, initially, the United States, Canada, Mexico and their respective territories and possessions, including, without limitation, Puerto Rico. Countries may be added to the Territory from time to time in accordance with the terms of Section 2.7.

1.1.42 "Third Party" means any Person other than WYETH, ACCESS and their respective Affiliates.

1.1.43 "Trademark" means any trademark, trade name, trade dress, slogan, logo, or similar item selected by WYETH for use in connection with the Product.

1.1.44 "WYETH" has the meaning set forth in the Preamble.

1.1.45 "WYETH Confidential Information" means all information, specifications, know-how and data pertaining to WYETH's business disclosed to ACCESS, its Affiliates or its

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Third Party manufacturer hereunder, including, without limitation, marketing and sales plans, artwork, formats, equipment, logos, drawings, customer lists, regulatory filings, correspondence with the FDA or any other Regulatory Authority, clinical study data, analytical data, operating procedures and all ordering and sales information.

1.2 Construction of Certain Terms and Phrases.

Unless the context of this Agreement otherwise requires, (i) words of any gender include each other gender; (ii) words using the singular or plural number also include the plural or singular number, respectively; (iii) the terms "hereof," "herein," "hereby" and derivative or similar words refer to this entire Agreement; (iv) the terms "Article" or "Section" refer to the specified Article or Section of this Agreement; and (v) Article and Section headings shall not affect the meaning or construction of any provision of this Agreement.

2. SUPPLY

2.1 Grant of License.

2.1.1 Subject to the terms and conditions of this Agreement, ACCESS hereby grants to WYETH (a) the exclusive right and license in the Field under ACCESS's Intellectual Property Rights to market, offer for sale, sell and import products, including the Product, in the Territory, (b) the exclusive right and license in the Field under ACCESS's Intellectual Property Rights to use the Product in the Territory, provided that such right and license is limited to such use as is necessary for WYETH to market, offer for sale, sell, import and, subject to the terms and conditions set forth in Section 2.6, Manufacture the Product in the Territory, and (c) a non-exclusive right and license to use the Product and all information and Intellectual Property Rights with respect thereto (including, without limitation, data, studies and clinical trials) solely for the purpose of obtaining Regulatory Approvals for the Product. Except as expressly granted herein, ACCESS retains all rights in the Intellectual Property Rights and the Product.

2.1.2 Except as specifically provided to the contrary in Section 2.1.1, the license granted in Section 2.1.1 shall not

be construed (a) to effect any sale of ACCESS's Intellectual Property Rights or any other proprietary ACCESS technology; (b) subject to the terms and conditions set forth in Section 2.6, to grant any license relating to ACCESS's methods of formulating, fabricating and Manufacturing the Product; (c) to grant WYETH any rights in or to the use of the Intellectual Property Rights by implication or otherwise. WYETH shall mark or have marked all containers or packages of the Product in accordance with the patent marking laws of the jurisdiction in which such units of Product are to be used or distributed.

2.1.3 Upon expiration of the Term in any country due solely to the expiration of the last-to-expire patent within the Patents in such country, WYETH shall have a non-exclusive, fully paid up license to those licenses set forth in Section 2.1.1.

2.1.4 Subject to the terms and conditions of this Agreement, ACCESS hereby grants to WYETH an exclusive, non-transferable (except in accordance with a permitted

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assignment of this Agreement under Section 13.3) license in the Field to use ACCESS's "ORADISC" trademark (the "Mark") solely in connection with the production, marketing and sale of the Product under this Agreement, within the Territory. Based on the information provided by ACCESS, WYETH acknowledges that ACCESS is the exclusive owner of the Mark and all associated goodwill and registrations. WYETH agrees that it has no rights to use the Mark except for the right to use the Mark as provided for in this Agreement and all uses of the Mark by WYETH, and the associated goodwill, shall inure solely to the benefit of ACCESS. WYETH further agrees that upon the termination or expiration of this Agreement, all right to use the Mark provided to WYETH hereby shall revert fully to ACCESS. WYETH shall faithfully reproduce the Mark's design and appearance, as such design and/or appearance may be modified from time to time by ACCESS. WYETH shall not modify the design or appearance of the Mark unless requested to do so in writing by ACCESS. All uses of the Mark shall be subject to ACCESS's prior written approval on the basis of samples submitted by WYETH and shall be made in strict conformance with such specifications as ACCESS shall establish, as such specifications may be modified by ACCESS from time to time. All displays of the Mark shall bear such trademark notices as ACCESS shall require. Except as consistently with this Agreement with respect to the Product, WYETH shall not (a) use the Mark as part of, or in conjunction with, any other names or marks without ACCESS's prior written approval; (b) use the Mark or any confusingly similar marks, terms or designs, except as expressly authorized in this Section 2.1.4; (c) attempt to register any such marks, terms or designs; (d) take any actions inconsistent with ACCESS's ownership of the Mark and any associated registrations, or attack the validity of the Mark, ACCESS's ownership thereof, or any of the terms of this Section 2.1.4; (e) use the Mark in any manner that would indicate WYETH is using such Mark other than as a licensee of ACCESS; nor (f) assist any Affiliate or Third Party to do any of the same. ACCESS, and/or its authorized agents or representatives, shall have the right from time to time, upon reasonable notice to WYETH, to inspect WYETH's (or its contractors') facilities and operations during regular business hours, that are involved in the Manufacture of the Product pursuant to Section 2.6; provided that such inspections shall be subject to, and ACCESS shall require its authorized agents and representatives to agree in writing to, the confidentiality provisions set forth in Section 9 of this Agreement. Upon ACCESS's request, WYETH shall provide ACCESS with examples of all uses of the Mark as actually used by WYETH, and a reasonable number of actual samples of the goods produced, marketed and sold by WYETH under the Mark. WYETH agrees to cooperate with and offer reasonable assistance to ACCESS in facilitating ACCESS's control of the quality of the Product (and associated labels and marketing materials and other documentation) branded with the Mark hereunder.

2.2 Manufacture; Marketing.

Subject to Section 2.3, ACCESS shall Manufacture and deliver the Product to WYETH in such quantities and at such times as ordered by WYETH in accordance with this Agreement. During the Term, ACCESS shall maintain the resources necessary to Manufacture the Product and shall provide, at its own expense, all Materials and labor necessary to do so. WYETH shall market and sell the Product in each country in the Territory; provided that, nothing shall require WYETH to continue to market or sell the Product in any country within the Territory during a period of time that WYETH determines, in its sole judgment, that such

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Product is reasonably likely to be subject to adverse regulatory or legal action, or infringe any intellectual property right of any Third Party in such country; and provided further that, in the event that, commencing as of the third Contract Year, the royalties paid by WYETH to ACCESS under Section 5.5 do not, in the aggregate, equal or exceed * Dollars (US\$ *) for any Contract Year, then ACCESS shall have, as its sole and exclusive remedy, the right to convert the rights and licenses granted to WYETH under this Agreement to non-exclusive rights and licenses by delivery of written notice to such effect. WYETH shall have the right to purchase the Product in the final packaged form described in Section 5.1; provided that in the event of a Shortfall (as hereinafter defined) WYETH shall have the right to purchase the Product in bulk and package the Product itself or arrange for a Third Party to package the Product.

2.3 Forecasts.

At least four (4) months prior to Launch, WYETH shall submit to ACCESS a forecast of the quantity of the Product that WYETH anticipates ordering from ACCESS prior to WYETH's anticipated Launch of Product. WYETH shall submit to ACCESS a forecast of the quantity of the Product that WYETH anticipates ordering from ACCESS during the twelve (12) month period (broken down by month) following Launch and WYETH shall update such forecast on a rolling twelve (12) months basis every month thereafter (each, a "Rolling Forecast"). WYETH shall place purchase orders for at least the quantity of the Product specified in the first three (3) months of each such Rolling Forecast and the remaining nine (9) months shall be a non-binding good faith estimate. Except as set forth in this Section 2.3 or in Section 8.8, WYETH shall not be required to order any fixed minimum quantity of the Product or any quantity of the Product, notwithstanding any forecast or prior course of dealing.

2.4 Orders and Delivery.

WYETH shall place its firm orders for the Product with ACCESS by submitting a purchase order, at least ninety (90) days prior to the delivery date requested therein, which sets forth (a) the quantity of the Product ordered for delivery; and (b) the delivery date for that order. Any such purchase order which is in accordance with the terms and conditions of this Agreement shall be deemed to be accepted by ACCESS. For all other purchase orders placed by WYETH, unless ACCESS notifies WYETH in writing within fifteen (15) days of receipt of a purchase order that it is unable to deliver the Product in accordance with such purchase order, ACCESS shall be deemed to have accepted such purchase order as a binding order. If ACCESS notifies WYETH that it is unable to fill a purchase order that is not in accordance with the terms and conditions of this Agreement, it shall indicate the portion of such purchase order ACCESS cannot supply by the requested delivery date and specify alternate delivery dates; provided that in the event that WYETH delivers a purchase order less than ninety (90) days prior to the requested delivery date, ACCESS shall use commercially reasonable efforts to meet such requested delivery date despite

the shortened lead time, and ACCESS will not be in breach of its obligations hereunder if, despite such commercially reasonable efforts, ACCESS is not able to meet such requested delivery date with respect to such order.

* - Confidential portions have been omitted and are on file separately with the Commission.

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WYETH may cancel or modify any firm purchase order (in whole or in part) at any time prior to the delivery for any quantity of Product for which Manufacturing has not been completed pursuant to such purchase order at the time that notice of cancellation or modification is received by ACCESS; provided that if Manufacturing has commenced but not completed pursuant to such firm purchase order, WYETH shall reimburse ACCESS for Material and labor costs in respect of any works-in-progress pursuant to such cancelled or modified purchase order (or part thereof) at the time notice of cancellation or modification is received by ACCESS; and provided, further, that WYETH shall reimburse ACCESS for the actual, reasonable out-of-pocket cost of any other Material purchased by ACCESS to fill a cancelled purchase order (or part thereof) that are unique to the Product and cannot within a reasonable period of time otherwise be used in ACCESS's operations. All Product shall be delivered F.O.B. the Facility and in accordance with WYETH's instructions. Title, possession and risk of loss shall pass to WYETH upon delivery of Product to WYETH's designated carrier at the Facility's loading dock. The provisions of this Agreement shall prevail over any inconsistent statement or provisions contained in any document related to this Agreement passing between the parties hereto including, but not limited to, any purchase order, acknowledgment, confirmation or notice.

2.5 Shelf Life.

ACCESS shall schedule Manufacturing operations so that all of the Product delivered has the latest expiry date possible, and in no event shall any Product be delivered to WYETH with an expiry date less than the maximum established expiry date (as set forth in the Specifications) less three (3) months. If Product is delivered to WYETH whose expiry date does not conform with the requirements set forth in this Section 2.4, ACCESS shall promptly, at its sole expense, replace the non-conforming Product.

2.6 Alternative Supply.

Notwithstanding any provision herein to the contrary, in the event that (1) ACCESS is in default of its supply obligations under this Agreement with respect to three (3) accepted WYETH purchase orders within any twelve month period (a "Shortfall"), or (2) if during Manufacture or supply of the Product to WYETH there is a material violation of the requirements set forth in Sections 2.9, 3.1, 3.2, 3.4, 3.6, 3.8 or the representations set forth in Sections 6.2.1, 6.2.4 or 6.2.5 (a "Regulatory Shortfall") that is not cured within forty-five (45) days of the later to occur of the (i) date of the violation or (ii) notice to ACCESS of such violation, then WYETH, in addition to any other rights and remedies it may have, shall have the right to Manufacture the Product itself and/or qualify an alternative supplier of Product. ACCESS shall, at its cost, (a) cooperate with WYETH in the transfer of copies of the Confidential Information, technology and know-how necessary to Manufacture the Product to WYETH and/or its designated alternative supplier, (b) deliver to WYETH copies of such drawings, specifications, and other information in ACCESS's possession as may be necessary to Manufacture the Product or cause the Product to be Manufactured and (c) grant to WYETH a limited license in the Field under ACCESS's Intellectual Property Rights during the Term of this Agreement to Manufacture, make, or have made for WYETH's distribution of the Product in the Territory, the Product; provided that to the extent that such

technology and know-how constitutes ACCESS Confidential Information (or any information constitutes Confidential Information of

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ACCESS's Third Party manufacturer) it shall be subject to the provisions of Article 9 and WYETH's designated alternative supplier shall be required to enter into a confidentiality agreement with ACCESS containing substantially the same terms as Article 9; and further provided that all items provided under clauses (a) and (b) above will be subject to the license granted pursuant to clause (c). In addition to WYETH's aforementioned right to Manufacture the Product itself and/or qualify an alternative supplier of the Product by reason of a Shortfall, WYETH shall be relieved of its obligation to order its purchase requirements of the Product from ACCESS if ACCESS, for any reason, is unable, anticipates that it will be unable or is unwilling to supply Product meeting WYETH's forecasted requirements for a period of time of three (3) months until such ability or willingness to supply resumes; provided that WYETH shall continue to be relieved of its obligation to order its purchase requirements of Product from ACCESS to the extent necessary to fulfill any reasonable contractual commitment entered into during such period and to the extent that it has accumulated an inventory of Product during such period. In the case of a Regulatory Shortfall, WYETH shall immediately be relieved of any obligation to order its purchase requirements of the Product from ACCESS and shall not be required to purchase or accept any Product from ACCESS until and unless the Regulatory Shortfall has been remedied. In the event that WYETH elects to manufacture the Product itself and/or qualify an alternative supplier of the Product in accordance with this Section 2.6, then ACCESS shall reimburse WYETH for WYETH's reasonable additional cost in obtaining and establishing an alternative supplier.

2.7 Expansion of the Territory.

At any time during the initial twelve (12) months of the Term of this Agreement, WYETH shall have the right and option to negotiate for the addition of countries or geographic areas to the Territory. Such right is exercisable by delivery of written notice to ACCESS, specifying the countries or geographic areas with respect to which WYETH would like to add to the Territory, and is subject to mutual agreement of the Parties. Upon receipt of such notice, the Parties shall negotiate in good faith the terms of the exclusive or non-exclusive (as the parties may mutually agree) arrangement with respect to the additional countries or geographic areas. In the event that the Parties are unable to reach agreement on such terms on or prior to the 60th day following commencement of such negotiations, ACCESS shall bear no further obligation to WYETH under this Section 2.7 with respect to the applicable countries or geographic area; provided that ACCESS shall not thereafter enter into or be a party to any arrangement, agreement, license or distribution relationship with a Third Party with respect to the Product in all or any portion of the applicable countries or geographic areas on terms and conditions in the aggregate more favorable to such Third Party than the aggregate terms and conditions offered to WYETH without first offering such aggregate terms and conditions to WYETH.

2.8 Non-Compete.

During the Term, neither WYETH nor any Affiliate of WYETH may directly or indirectly market, offer for sale, sell, import or distribute in the Territory any human, over-the-counter, mucoadhesive, erodible product in the Field and in the form of the Product other than the Product. For the avoidance of doubt, this Agreement shall not preclude WYETH from

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continued manufacture and sale of any product which was marketed, offered for sale, sold, imported or distributed by WYETH as of the Effective Date.

2.9 Third-Party Manufacturer.

ACCESS shall, in accordance with the terms of this Section 2.9, establish a Manufacturing Facility (operated by a Third Party manufacturer) in compliance with the FDA's requirements, including, without limitation, compliance with the written requirements of WYETH as provided as of the Effective Date. As of the Effective Date, ACCESS has identified to WYETH the Third Party manufacturer it intends to use to Manufacture and supply to WYETH the Product and the location of the Facility. ACCESS shall promptly provide WYETH with access to the Facility for inspection by WYETH. In addition, ACCESS shall promptly provide WYETH with information requested by WYETH regarding the Third Party manufacturer (including, without limitation, any information requested by WYETH in accordance with WYETH's due diligence, its GMP audit procedures and its "Level One Compliance Assessment"). During the Term and upon reasonable prior notice to ACCESS, WYETH shall have the right, from time to time, to audit the Facility and the performance of the Third Party manufacturer to ensure that the Facility and the Third Party manufacturer are in compliance with GMP and WYETH's other manufacturing standards. Any such audits or inspections shall be undertaken by WYETH in accordance with the provisions of Section 3.5.

2.10 Development Plan.

ACCESS and WYETH acknowledge and agree that, as of the Effective Date, the Product has not been fully developed and is still in the "prototype" stage of product development. The Parties, on or prior to March 31, 2004, shall mutually agree upon a development plan, which development plan shall include, without limitation, (a) the stages of development set forth in Exhibit B hereto (and shall be based upon the development program model set forth therein). The final development plan shall also include, at times mutually agreed upon by the Parties the (a) the mutually agreed upon Methods of Analysis, and (b) the mutually agreed upon Specifications. Once the Parties have mutually agreed upon a final development plan, ACCESS shall, at its own cost and expense (unless and to the extent otherwise indicated in the final development plan), use commercially reasonable efforts to implement each of the stages of such development plan in accordance with such development plan. Each of such stages must be completed in accordance with the applicable specifications or criteria before Launch will occur.

2.11 Additional Responsibilities.

2.11.1 ACCESS shall be responsible for (a) at WYETH's cost and expense, supplying to WYETH, prior to the commencement of Manufacturing of the Product, a full scale validation Batch and the data reasonably requested by WYETH (including, without limitation, the final Product formulation, the processing requirements from start to finish for all production, the validated analytical methods, the Specifications and test method (both chemical and physical) for all elements of the disc component and the Product through the finished production of the Product and the validation protocols and schedules for processes, equipment, cleaning and

packaging) and WYETH shall reimburse ACCESS for ACCESS's actual, reasonable, out-of-pocket costs for the supply of such Batch and data, (b) at WYETH's cost and expense, scale-up, validation and stability of the Product for commercial production of the Product, including, without limitation, bulk production of the * , production of the * and development and validation of a mutually acceptable package configuration, (c)

cooperating with WYETH with respect to the obtaining by WYETH of any Regulatory Approvals required to be obtained by WYETH with respect to the marketing, sale, offering to sell, importing and/or distribution of the Product, and (d) providing to WYETH complete Batch records for all validation Batches and, on an annual basis, providing one representative full Batch record.

2.11.2 WYETH shall be responsible, at WYETH's cost and expense, for any clinical trials, consumer product testing and commercialization of the Product, including, without limitation, all sales and marketing activities related to the Product and the design of all Product packaging and related artwork, and the design of all labeling.

2.11.3 WYETH shall retain, at its own expense a selling and service organization with adequate experience, ability and training for purposes of marketing and selling the Product in the Territory.

2.12 ACCESS Manufacturing and Supply Obligations. It is understood and agreed by the Parties that ACCESS will be entering into an agreement with a Third Party manufacturer to perform the Manufacturing and supply obligations that ACCESS has under this Agreement. In accordance with such understanding, ACCESS acknowledges and agrees that with respect to ACCESS's obligations to WYETH under this Agreement (a) despite the performance by the Third Party manufacturer of ACCESS's Manufacturing and supply obligations hereunder, ACCESS shall be fully responsible for the performance of such as though it were performing such Manufacturing and supply obligations itself, (b) all of the provisions of this Agreement (including, without limitation, indemnification) shall be interpreted in such a way as to impute any actions or omissions by the Third Party manufacturer to ACCESS, and (c) except with respect to any matters falling within the scope of Section 10, ACCESS shall not be relieved or excused of any of its obligations hereunder due to any action or failure to act by the Third Party manufacturer. For avoidance of doubt, with respect to the obligations of ACCESS regarding Manufacture and supply to WYETH of the Product, reference to ACCESS in this Agreement shall also mean ACCESS's contractors, Third Party manufacturer and Affiliates.

3 COMPLIANCE, QUALITY AND ENVIRONMENTAL

3.1 Compliance with Law.

ACCESS shall conduct all Manufacturing hereunder in a safe and prudent manner, in compliance with all applicable laws and regulations (including, without limitation, those dealing with occupational safety and health, those dealing with public safety and health, those dealing with protecting the environment, and those dealing with disposal of wastes), and in

* - Confidential portions have been omitted and are on file separately with the Commission,

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compliance with all applicable provisions of this Agreement. ACCESS shall obtain and maintain all necessary Regulatory Approvals with respect to the Manufacture and supply to WYETH of the Product. To the extent necessary for the Regulatory Approval of the Product, ACCESS, shall permit the inspection of its premises and the Facility by Regulatory Authorities and shall supply all documentation and information requested by WYETH or such Regulatory Authority to obtain or maintain Regulatory Approval of the Product.

3.2 Manufacturing Quality; Storage.

All Product shall be Manufactured by ACCESS at the Facility using Materials and processing aids free of animal derived materials. ACCESS shall sample and analyze all Materials upon

receipt to ensure that such Materials are unadulterated, free of defects and meet the applicable Specifications therefor. ACCESS shall take all necessary steps to prevent contamination and cross contamination of Product. The Product shall be unadulterated and free from contamination, dilutents and foreign matter in any amount in accordance with the Product specifications and generally accepted pharmaceutical standards. ACCESS shall perform the quality control tests (both when the Product is in-process and when it is finished) with respect to the Product in accordance with the Methods of Analysis, the cost of such to be included in the price hereinafter specified. ACCESS shall promptly, upon completion of such tests, deliver to WYETH a copy of the record of such tests performed on, and a Certificate of Analysis for, each Batch of Product. ACCESS shall deliver a representative sample from each Batch of Product to WYETH's designated representative by the date reasonably specified by such representative. Within thirty (30) days of the Effective Date, each of the Parties shall execute and deliver the Quality Agreement substantially in the form of Exhibit C and as mutually agreed to by the parties. Each Party agrees to perform its respective obligations under the Quality Agreement in accordance with such agreement. Prior to shipment, the Product shall be stored at all times in conditions at least as favorable as those set forth on the Product's label, or in accordance with conditions reasonably specified by WYETH.

3.3 Testing by WYETH.

WYETH may test the Product samples in accordance with the applicable Methods of Analysis. If the analysis of any Product performed by or for WYETH differs from ACCESS's analysis of the same Batch, WYETH shall advise ACCESS and ACCESS and WYETH agree to consult with each other in order to explain and resolve the discrepancy between each other's determination. If, after good faith attempt by the Parties to do so, such consultation does not resolve the discrepancy, an independent, reputable laboratory as mutually agreed by the Parties shall repeat the applicable Methods of Analysis on representative samples from such Batch provided by both ACCESS and WYETH. The costs of the independent laboratory referred to above shall be borne by (a) WYETH if such laboratory determines that the Product conforms to the Specifications or (b) ACCESS if such laboratory determines that the Product does not conform to the Specifications. If so requested by WYETH in writing, ACCESS shall promptly send a new Batch of the Product (of similar quantity as to the amount of such Product being analyzed as set forth above) to WYETH. WYETH shall not be obligated to pay for any of the Product (and if WYETH has paid for such Product ACCESS shall promptly reimburse WYETH

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for the cost of replacing such Product, including, without limitation, related costs such as testing and transportation costs) that such laboratory determines does not conform to the Specifications, but shall be obligated to pay for any new Batch of Product that is sent as specified above; provided that WYETH must destroy (and certify destruction of) such non-conforming Product.

3.4 Samples and Record Retention.

ACCESS shall retain records and retention samples of each Batch of the Product for at least thirty-eight (38) months after the expiration date of that Batch and shall make the same available to WYETH upon request. Retention samples shall only be destroyed after the required holding period; provided that in the event that WYETH provides written notice to ACCESS during such thirty-eight (38) month period that it desires ACCESS to retain such retention samples for a longer period of time, then ACCESS shall comply with such request until notified by WYETH that the sample need no longer be retained. During and after the Term of this Agreement ACCESS shall reasonably assist WYETH with respect to any complaint, issue or investigation relating to the Product.

3.5 Inspection.

ACCESS shall give access to representatives of WYETH, at all reasonable times during regular business hours, to the Facility and any other facility

in which Product is Manufactured, tested, packaged and/or stored, and to all Manufacturing records with respect to the Product, for the purpose of inspection. WYETH shall have the right while at any such Facility to inspect and copy (provided that to the extent that such copies constitute ACCESS Confidential Information (or Confidential Information of ACCESS's Third Party Manufacturer) they shall be subject to the provisions of Article 9) records and Regulatory Approvals solely to evaluate work practices and compliance with all applicable FDA and other Regulatory Authority laws and regulations, occupational health and safety, and environmental laws and regulations, GMP and warehousing practices and procedures. The conduct of (or right to conduct) any inspection under this Section 3.5 does not impose upon WYETH responsibility or liability for the operation of the Facility. Such inspection shall be conducted after prior written notice to ACCESS, will be conducted consistently with the WYETH policies and procedures provide to ACCESS as of the Effective Date (and as such policies and procedures are modified and provided in writing to ACCESS from time to time, which modified policies and procedures shall not conflict with any of the provisions of this Agreement) and in a manner that is not disruptive to ACCESS's operations, and shall not be more frequent than is reasonable.

3.6 Adverse Drug Experience Reporting.

Each Party shall fully, accurately and promptly provide the other Party with all data known to it at any time during the Term of this Agreement or thereafter, which data indicate that any Product is or may be unsafe, lacks utility, or otherwise does not meet the Specifications in accordance with the Adverse Event Reporting Procedures set forth in Exhibit D attached hereto (as the same may be amended from time to time by notice in writing from WYETH to ACCESS; provided that such amendment shall not conflict with any of the provisions of this

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Agreement). WYETH shall determine whether such information is required to be reported to the FDA and any other Regulatory Authority.

3.7 Recalls and Seizure.

3.7.1 Each Party shall keep the other Party promptly and fully informed of any notification or other information whether received directly or indirectly which might result in the Recall or Seizure of the Product. If either Party determines that it is necessary to Recall any Product, it shall immediately notify the other Party and, prior to commencing any Recall, the Parties shall consult with one another to determine whether or not a Recall is necessary. If it is mutually agreed that a Recall is necessary (or if WYETH determines, in its sole discretion, that a Recall is necessary), then the parties shall meet and determine the manner in which the Recall is to be carried out and review any instructions or suggestions of the applicable Regulatory Authorities. ACCESS and WYETH shall effect the Recall in the manner agreed upon between the Parties in as expeditious a manner as possible and in such a way as to cause the least disruption to the sales of any Product and to preserve the goodwill and reputation associated with the Product. In any such situation, WYETH shall have the right to make all final decisions regarding such Recall.

3.7.2 In the event that a Recall results from any cause or event arising from ACCESS's breach of Sections 2.9, 3.1, 3.2, 3.4, 3.6, 3.8 or the representations set forth in Sections 6.2.1, 6.2.4 or 6.2.5 and/or the defective Manufacture, storage or handling of the Product by ACCESS (excluding defects relating to packaging or labeling supplied by or prepared at and in accordance with the direction of WYETH), ACCESS shall be responsible for all expenses of the Recall incurred by WYETH and ACCESS shall promptly replace such Product at no additional cost to WYETH consistent with directions received from the appropriate Regulatory Authority. In the event that a Recall results from any cause or event arising from defective Manufacture, storage, handling, or distribution of the Product by WYETH or its Affiliates, distributors or contractors (including but not limited to defective Manufacture, storage, handling or distribution undertaken at the direction of WYETH and consistently with WYETH's instructions), WYETH shall be responsible for the expenses of the Recall, including the cost of replacement Product. For the purposes of this Agreement, the expenses of a Recall shall include, without limitation, the expenses of notification and destruction or return of the recalled Product

and all other costs incurred in connection with such Recall, including reasonable costs and attorneys' fees, but shall not include lost profits of either party.

3.8 Environmental, Occupational Health and Safety.

3.8.1 ACCESS shall promptly report to WYETH after any of the following incidents related to the Manufacturing operations hereunder occurs: (a) fatalities and/or significant injuries or occupational illness; (b) property damage in excess of \$50,000; (c) inspections by any environmental protection agency or occupational health and safety agency; or (d) requests for information, notices of violations or other significant governmental and safety agency communications relating to environmental, occupational health and safety compliance.

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3.8.2 ACCESS shall only use waste haulers, brokers and disposal sites which WYETH has approved in writing for hazardous waste generated by the Manufacturing operations. As between ACCESS and WYETH, ACCESS shall have title to and be responsible for disposing in an environmentally safe manner all residue and waste resulting from the Manufacturing operations performed hereunder. ACCESS shall not use WYETH trademarks or trade dress to identify any waste materials or residues.

4. MANUFACTURING CHANGES

4.1 Voluntary Changes.

ACCESS shall not make, nor shall any other Person make, any changes to the Manufacturing process, the Manufacturing equipment, the Specifications, the Materials, the sources of Materials or the Methods of Analysis without the prior written consent of WYETH. If either Party requests in writing a change in the Manufacturing process, the Manufacturing equipment, the Specifications, the Materials, the source of Materials or Methods of Analysis with respect to the Product that is not the result of a requirement of the FDA or any other Regulatory Authority, the other Party shall use commercially reasonable efforts to make or accept such change, as the case may be. The requesting Party shall provide the other Party with a detailed written report of all proposed changes to the Manufacturing process, the Manufacturing equipment, the Specifications, the Materials, the sources of Materials or the Methods of Analysis.

4.2 Required Changes.

If the FDA or any other Regulatory Authority requests or requires, or takes any action that requires, any change in the Manufacturing process, the Manufacturing equipment, the Specifications, the Materials, the source of Materials or Methods of Analysis with respect to the Product, the Parties shall meet and discuss an implementation plan for such change and use commercially reasonable efforts to accommodate as soon as practicable such change to meet the FDA's or such other Regulatory Authority's requirements. Each Party will bear its respective costs associated with, or incurred as a result of, such change. Each Party agrees to promptly forward to the other copies of any written communication received by such Party from the FDA or any other Regulatory Authority that may affect the Manufacture, supply, or distribution of the Product as contemplated herein.

5. PRICE AND PAYMENT

5.1 Price.

ACCESS shall invoice WYETH for the Product supplied to WYETH hereunder at the applicable price per Product set forth on Exhibit E. The cost of the Product shall be comprised of four components: Materials, labor, fixed overhead and variable overhead. The cost of each such component will be set forth in Exhibit E within sixty (60) days after the Effective Date, and shall remain in effect unless and until the price of the Product is adjusted pursuant to this Article 5.

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5.2 Price Adjustment.

5.2.1 Commencing on any date in the second Contract Year, ACCESS may adjust the then-current price to reflect documented increases or decreases in labor costs, variable overhead costs or the acquisition cost of Materials per unit of Product at the beginning of the Contract Year in question as compared to the acquisition cost of such labor, variable overhead or Materials per unit of Product at the beginning of the immediately preceding Contract Year; provided that ACCESS gives WYETH not less than ninety (90) days' prior written notice of any price increase or decrease and that ACCESS may not increase the price more than once during any Contract Year; and provided, further, that except as provided in Section 5.2.2, any price increase per unit of Product shall not exceed the PPI Adjustment for the Contract Year in question. Until the effective date of such price increase, ACCESS shall supply WYETH such Product at the prices then in effect without such price increase. "PPI Adjustment" means for the Contract Year in question, the amount calculated in accordance with the following formula:

$$\frac{MC \times PPI - BPPI}{BPPI}$$

Where,

MC = the documented labor costs, variable overhead costs and the acquisition cost of all Materials per unit of Product at the beginning of the Contract Year immediately preceding the Contract Year in question;

BPPI = the Bureau of Labor Statistics Producer's Price Index for Pharmaceutical Preparations (Code 2834) for the first month of the Contract Year immediately preceding the Contract Year in question; and

PPI = the Bureau of Labor Statistics Producer's Price Index for Pharmaceutical Preparations (Code 2834) for the first month of the Contract Year in question.

Notwithstanding anything to the contrary contained in this Section 5.2.1, there shall be no price increases made due to any increases with respect to the fixed overhead component of the cost of the Product.

5.2.2 Notwithstanding anything to the contrary in Section 5.2.1, in the event of an extraordinary event that results in a documented material increase (with "material increase" meaning, for purposes of this Section 5.2.2, an increase of at least fifteen (15%) percent in the aggregate) in the collective cost of a major component of Manufacturing for the Product (as such components are set forth in Exhibit E) during any annual period after the end of the first Contract Year (an "Extraordinary Event Increase"), ACCESS need not wait until the next annual period to adjust the pricing for the Product. Upon ACCESS's determination that an Extraordinary Event Increase has occurred, ACCESS shall notify WYETH in writing of the applicable price adjustment, together with supporting documentation evidencing such change including without

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limitation, evidence that ACCESS shall have used its commercially reasonable efforts to secure alternative sources of supply for any components or consumables, at lesser costs without detracting from the quality or efficacy of the Product. Any such pricing adjustment will become effective thirty (30) days following the date of ACCESS's written notice thereof.

5.3 Continuous Improvement Price Adjustment.

Continuous improvement initiatives, mutually agreeable to the Parties shall be established annually to provide for attempting to achieve continuous cost reductions during the Term hereof. Continuous improvement teams consisting of equal representation from each Party shall use reasonable efforts to work to identify and implement cost savings at a targeted rate of five percent (5%) of WYETH's purchase price per Contract Year. Any documented savings shall be allocated to the Parties in proportion to the level of contribution by each party to realize the savings. Any cost savings allocated to WYETH shall be in the form of reduced purchase price, effective (with respect to any subsequent WYETH purchase orders) immediately upon documentation and allocation of the savings.

5.4 License Payments.

During the Term, the license payments set forth in Exhibit F shall be due and payable from WYETH to ACCESS within ten (10) days of the occurrence of the applicable milestone set forth in Exhibit F.

5.5 Royalty Payments.

In addition to the payments set forth above, WYETH shall pay to ACCESS a royalty (the "Royalty"), on a country-by-country basis in the Territory, equal to * percent (* %) of Net Sales of the Product in such country during each calendar quarter (or portion thereof) during the Term (each such period, a "Royalty Period"), commencing as of the date on which the Product is sold by WYETH for the first time to a Third Party for commercial distribution in such country. If, during the Term, in any country in the Territory, (a) another * (other than those containing amlexanox as an active ingredient) for oral pain (excluding sore throat pain) becomes commercially available, which has the same labeling and indications on the Product and which adversely impacts either the sales price or the unit volume by greater than * percent (* %), or (b) ACCESS exercises its rights under Section 2.2 to convert the exclusive license with respect to a country to a non-exclusive license, then the Royalty with respect to such country shall be immediately reduced to * percent (* %). Each Royalty will be payable not later than forty-five (45) days following the expiration of each applicable Royalty Period. WYETH shall pay the Royalty with respect to a country that accrues during the Term of this Agreement for so long as the license granted by ACCESS under Section 2.1.1 remains in effect in such country. WYETH will include with each such payment a written report detailing (i) the number of Product units, per country, and the sales price of such Product units by WYETH and its Affiliates; and (ii) Net Sales of the Product during the applicable Royalty Period, all in a manner consistent with WYETH's internal sales reporting.

* - Confidential portions have been omitted and are on file separately with the Commission.

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5.6 Payment.

WYETH shall pay invoices for Product delivered hereunder not later than thirty (30) days after the later of receipt of Product covered by such invoice and receipt of such invoice.

5.7 Taxes and Other Charges.

All Product prices are exclusive of taxes, shipping costs to the point of delivery, customs duties and other charges, and WYETH agrees to bear and be responsible for the payment of all such charges imposed, excluding taxes based upon ACCESS's net income.

5.8 Audit Rights.

5.8.1 WYETH shall have the right, at its own expense, to access the books and records of ACCESS and its Affiliates as may be reasonably necessary to verify the accuracy of the labor costs and Material costs referred to in Section 5.2. Such access shall be conducted after thirty (30) days' prior written notice to ACCESS and during ordinary business hours, will be conducted in a manner that is not disruptive to ACCESS's operations, and shall not be more frequent than once per Contract Year or in respect of any Contract Year ending not more than twenty-four (24) months prior to the date of such notice. Subject to Section 5.8.3, if such independent certified public accountant's report shows any overpayment by WYETH, ACCESS shall remit to WYETH within thirty (30) days after ACCESS's receipt of such report, (a) the amount of such overpayment, and (b) if such overpayment exceeds five percent (5%) of the total amount owed for the period then being audited, the reasonable fees and expenses of any independent accountant performing the audit on behalf of WYETH. Subject to Section 5.8.3, if such independent certified public accountant's report shows any underpayment by WYETH, WYETH shall pay to ACCESS within thirty (30) days after WYETH's receipt of such report, the amount of such underpayment. Any audit or inspection conducted under this Agreement by WYETH or its agents or contractors will be subject to the confidentiality provisions of this Agreement, and WYETH will be

responsible for compliance with such confidentiality provisions by such agents or contractors.

5.8.2 WYETH shall maintain books of account with respect to its sales of the Product in each country in the Territory. ACCESS shall have the right, not more than once during each calendar year, to have an independent accountant selected and retained by ACCESS to inspect and examine such books of WYETH during regular business hours for the purpose of verifying the statements of the aggregate Net Sales resulting from sales of Product and determining the correctness of the Royalties paid. Subject to Section 5.8.3, if such independent certified public accountant's report shows any underpayment by WYETH, WYETH shall pay to ACCESS within thirty (30) days after WYETH's receipt of such report, (a) the amount of such underpayment, and (b) if such underpayment exceeds five percent (5%) of the total amount owed for the period then being audited, the reasonable fees and expenses of any independent accountant performing the audit on behalf of ACCESS. Subject to Section 5.8.3, if such independent certified public accountant's report shows any overpayment by WYETH, ACCESS shall remit to WYETH within thirty (30) days after ACCESS's receipt of such report, the amount

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of such overpayment. Any audit or inspection conducted under this Agreement by ACCESS or its agents or contractors will be subject to the confidentiality provisions of this Agreement, and ACCESS will be responsible for compliance with such confidentiality provisions by such agents or contractors.

5.8.3 If any dispute arises under this Section 5.8 between the Parties relating to overpayments or underpayments, and the Parties cannot resolve such dispute within thirty (30) days of a written request by either Party to the other Party, the Parties shall hold a meeting, attended by the Chief Executive Officer or President of each party (or their respective designees), to attempt in good faith to negotiate a resolution of the dispute. If, within sixty (60) days after such meeting request, the Parties have not succeeded in negotiating a resolution of the dispute, either Party may pursue any other available remedy, including, upon prior written notice to the other Party, instituting legal action.

5.9 Late Payments.

If any payment due to ACCESS under this Agreement is not received by ACCESS within ten (10) days of the due date, then, commencing from the date on which such payment was due the amount of such payment shall accrue interest calculated at an annual rate equal to the prime rate plus two percent (2%) until such time as payment of the overdue amount is made in full; provided that no interest shall accrue on any amounts being disputed in good faith by WYETH with respect to which WYETH is making diligent and good faith efforts to resolve.

5.10 Currency Exchange.

All payments to be made pursuant to this Agreement shall be made in United States dollars. Amounts based on Net Sales in currencies other than United States dollars shall be converted on the last business day of each calendar month to United States dollars at the WYETH financial statement exchange rate applied by WYETH on a consistent basis in WYETH's own financial accounting.

6. REPRESENTATIONS AND WARRANTIES

6.1 Representation and Warranties of Each Party.

Each of WYETH and ACCESS hereby represents, warrants and covenants to the other Party hereto as follows:

6.1.1 it is a corporation or entity duly organized and validly existing under the laws of the state or other jurisdiction of incorporation or formation;

6.1.2 the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action and do not require any shareholder action or approval;

6.1.3 it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

6.1.4 the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (a) a loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (b) the provisions of its charter or operative documents or by laws; or (c) any order, writ, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound; and

6.1.5 it shall comply with all applicable laws and regulations relating to its activities under this Agreement.

6.2 Representations and Warranties of ACCESS.

ACCESS hereby further represents and warrants to WYETH that:

6.2.1 as of the date of each delivery of the Product by ACCESS to a carrier, the Product (a) has been Manufactured, stored and shipped in strict accordance with GMPs, all applicable laws, rules, regulations or requirements and all applicable Regulatory Approvals in effect at the time of Manufacture; (b) conforms to the Specifications and the Quality Agreement, and is free from defects and are merchantable; (c) is not adulterated or misbranded; and (d) has been shipped and stored in accordance with procedures requested by WYETH;

6.2.2 as of the date of each delivery of the Product by ACCESS to a carrier, ACCESS has good and marketable title to the Product and the Product is free from all liens, charges, encumbrances and security interests;

6.2.3 to ACCESS's actual knowledge as of the Effective Date, the Manufacture, use, importation, offer for sale and sale of the Product does not infringe any intellectual property rights of any Third Party within the Territory;

6.2.4 as of the date of each delivery of the Product by ACCESS to a carrier, neither ACCESS nor any Affiliate, contractor or Third Party manufacturer of ACCESS, used or uses in any capacity the services of any person debarred under the U.S. Generic Drug Enforcement Act, 21 USA %335a(k)(l) and further it did not use any person who has been convicted of a crime as defined under the Generic Drug Enforcement Act in connection with the Manufacture of Product;

6.2.5 as of the date of each delivery of the Product by ACCESS to a carrier, ACCESS possesses all necessary Regulatory Approvals relating to ACCESS's Manufacture and supply to WYETH of the Product;

6.2.6 as of the Effective Date, U.S. Patent No. * is existing and has not

* - Confidential portions have been omitted and are on file separately with the Commission.

been held to be invalid or unenforceable, in whole or in part;

6.2.7 as of the Effective Date, ACCESS is the sole and exclusive owner of the Intellectual Property Rights existing as of the Effective Date, all of which are free and clear of any liens, charges and encumbrances (other than any licenses granted by ACCESS to Third Parties, which grants do not conflict with the license grants to WYETH hereunder);

6.2.8 as of the Effective Date, and, except as disclosed to WYETH in writing, as of the date of each delivery of the Product by ACCESS to a carrier, ACCESS has received no notice that the practice of the Intellectual Property Rights or the Mark are subject to an infringement claim of any issued patent or Mark owned or possessed by any Third Party within the Territory;

6.2.9 as of the Effective Date, the Intellectual Property Rights are not the

subject to any funding agreement with any government or governmental agency; and

6.2.10 as of the Effective Date, or within ten (10) days thereof, ACCESS has provided WYETH with any and all information relating to the Product, its Manufacture and formulation necessary for WYETH to conduct a freedom to operate opinion relating to the Territory, and all information has been provided so that WYETH may complete its due diligence.

6.3 No Presumption.

Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption shall exist or be implied against the Party which drafted such terms and provisions.

6.4 Remedy.

As WYETH's sole and exclusive remedy for any breach of Section 6.2.1 discovered prior to the distribution by WYETH or its Affiliates of the applicable Product, ACCESS shall promptly replace, at its sole cost and expense, any Product which fails to comply with the representations set forth in Section 6.2.1; provided that such non-conforming Product shall be returned to ACCESS in accordance with ACCESS's return procedures, and only if after ACCESS's inspection, such Product is determined to have been non-conforming pursuant to the procedures set forth in Section 3.3. Except as otherwise provided expressly in this Agreement, each Party is free to seek legal and equitable recourse against the other in the event of any breach of this Agreement (including, without limitation, any breach of such other Party's obligations, representations, or warranties under this Agreement), subject to the limitations of liability set forth in Section 6.7 and, in such case, the breaching party shall be liable for all damages, losses, liabilities, expenses or penalties (excluding attorneys' fees and expenses) incurred, assessed or sustained by or against the non-breaching party, its Affiliates, directors, officers, employees or agents arising out of such breach.

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6.5 WYETH Responsibility.

WYETH shall not be responsible for any loss or cost incurred by ACCESS during Manufacture of the Product in compliance with the requirements of Section 6.2.1.

6.6 Disclaimer.

6.6.1 THE FOREGOING WARRANTIES ARE THE SOLE AND EXCLUSIVE WARRANTIES GIVEN BY ACCESS WITH RESPECT TO THE PRODUCTS AND SERVICES PROVIDED HEREUNDER, AND ACCESS GIVES AND MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, OTHER THAN THE FOREGOING. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, EXCEPT FOR THE WARRANTIES EXPRESSLY PROVIDED IN SECTION 6, NO IMPLIED WARRANTY OF MERCHANTABILITY, VALIDITY, NON-INFRINGEMENT, TITLE, FITNESS FOR ANY PARTICULAR PURPOSE, AND NO IMPLIED WARRANTY ARISING BY USAGE OF TRADE, COURSE OF DEALING OR COURSE OF PERFORMANCE IS GIVEN OR MADE BY ACCESS OR SHALL ARISE BY OR IN CONNECTION WITH ANY SALE OR PROVISION OF PRODUCTS OR SERVICES BY ACCESS, OR WYETH'S USE OR SALE OF THE PRODUCT, OR ACCESS'S AND/OR WYETH'S CONDUCT IN RELATION THERETO OR TO EACH OTHER. NO REPRESENTATIVE OF ACCESS IS AUTHORIZED TO GIVE OR MAKE ANY OTHER REPRESENTATION OR WARRANTY OR TO MODIFY THE FOREGOING WARRANTY IN ANY WAY.

6.6.2 EXCEPT FOR THE WARRANTIES GIVEN BY WYETH AS EXPRESSLY PROVIDED IN SECTION 6, WYETH GIVES AND MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND OR NATURE, EXPRESS OR IMPLIED, WITH RESPECT TO THE

MATTERS ADDRESSED IN THIS AGREEMENT.

6.6.3 The warranties set forth in this Section 6 do not apply to any non-conformity of the Product resulting from (a) repair, alteration, misuse, negligence, abuse, accident, mishandling or storage in an improper environment by any party other than ACCESS (or its contract manufacturer), or (b) use, handling, storage or maintenance other than in accordance with Product Specifications or Product label.

6.7 Limitation of Liability.

ACCESS'S LIABILITY, AND THE EXCLUSIVE REMEDY, IN CONNECTION WITH THE SALE OR USE OF THE PRODUCT (WHETHER BASED ON CONTRACT, NEGLIGENCE, BREACH OF WARRANTY, STRICT LIABILITY OR ANY OTHER LEGAL THEORY), SHALL BE STRICTLY LIMITED TO ACCESS'S OBLIGATIONS AND WYETH'S RIGHTS AS SPECIFICALLY AND EXPRESSLY PROVIDED IN THIS AGREEMENT.

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IN NO EVENT WHATSOEVER SHALL EITHER PARTY HAVE ANY LIABILITY, OBLIGATION OR RESPONSIBILITY TO THE OTHER PARTY OR SUCH OTHER PARTY'S AFFILIATES FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES ARISING IN ANY WAY IN CONNECTION WITH PRODUCT OR ITS PURCHASE, SALE, USE OR INABILITY TO USE.

7. INDEMNIFICATION AND INSURANCE

7.1 Indemnification.

7.1.1 ACCESS shall defend, indemnify and hold harmless WYETH, its Affiliates, directors, officers, employees and agents from and against all damages, losses, liabilities, expenses, claims, demands, suits, penalties or judgments or administrative or judicial orders (including, without limitation, reasonable attorneys' fees and expenses) incurred, assessed or sustained by or against WYETH, its Affiliates, directors, officers, employees or agents with respect to a claim by a Third Party arising out of (a) the negligent acts or omissions of ACCESS; (b) any breach by ACCESS of this Agreement or its representations, warranties or covenants hereunder; (c) any Recall or Seizure attributable to ACCESS's performance (including, without limitation, amounts WYETH pays or credits to its customers for Product so Recalled or Seized); (d) product liability, tort, nuisance or other claim arising out of the defective manufacture, storage or supply of the Product by ACCESS; (e) any allegation that the manufacture, importation, sale, offer for sale or use of the Product infringes any patent or other intellectual property, proprietary or protected right within the Territory; provided that ACCESS will not be obligated to indemnify WYETH if and to the extent that the alleged infringement is caused by: (i) WYETH's (including, without limitation, its Affiliates, agents, contractors, and sub-distributors) or its customers misuse or modification of the Product; or (ii) WYETH's (including, without limitation, its Affiliates, agents, contractors, and sub-distributors) or its customers use of the Product in combination with any products or materials not provided by ACCESS; and further provided that if the Product is held to constitute an infringement or misappropriation of any Third Party's intellectual property rights or if in ACCESS's opinion, the Product is, or is likely to be held to constitute, an infringement or misappropriation, ACCESS may at its expense and option: (x) procure the right for WYETH to continue distributing the Product; (y) upon prior approval by WYETH, which approval will not be unreasonably withheld or delayed, promptly replace the Product with a non-infringing and non-misappropriating equivalent product conforming to the applicable Product Specifications and Regulatory Approvals; provided that there shall not be any material delay in any such replacement; or (z) upon prior approval by WYETH, which approval will not be unreasonably withheld or delayed, modify the Product to make it non-infringing and non-misappropriating while conforming to the applicable Product Specifications and Regulatory Approvals; provided that there shall not be any material delay in any such modification; (f) any enforcement or other action by any Regulatory Authority relating to the Manufacture, the pricing of the Product by ACCESS to WYETH or sale of the Product by ACCESS to WYETH; or

(f) ACCESS's failure to comply with any applicable law, regulation or order (including, without limitation, environmental laws, regulations and orders). The foregoing indemnification obligation shall not apply in the event and to the extent that such claim arose as a

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result of any indemnitee's negligence, intentional misconduct or breach of this Agreement. The provisions of this Section shall survive the termination or expiration of this Agreement.

7.1.2 WYETH shall defend, indemnify and hold harmless ACCESS, its directors, officers, employees and agents from and against all damages, losses, liabilities, expenses, claims, demands, suits, penalties or judgments or administrative or judicial orders (including, without limitation, reasonable attorneys' fees and expenses) incurred, assessed or sustained by or against ACCESS, its directors, officers, employees or agents with respect to a claim by a Third Party arising out of (a) the negligent acts or omissions of WYETH; (b) any breach by WYETH of this Agreement or of its representations, warranties or covenants hereunder; (c) any allegation that the Trademarks or WYETH's packaging or WYETH's (or any Affiliate of WYETH's) marketing materials infringes any patent or other proprietary or protected right of any Third Party; (d) any Recall or Seizure attributable to WYETH's performance; (e) any enforcement or other action by any Regulatory Authority relating to the distribution, the pricing of the Product by WYETH or sale of the Product by WYETH to Third Parties; (f) WYETH's failure to comply with any applicable law, regulation or order (including, without limitation, environmental laws, regulations and orders), or (g) the marketing and distributing of the Product by WYETH, its Affiliates or sub-distributors. The foregoing indemnification obligation shall not apply in the event and to the extent that such claim arose as a result of any indemnitee's negligence, intentional misconduct or breach of this Agreement. The provisions of this Section shall survive the termination or expiration of this Agreement.

7.1.3 To receive the benefit of indemnification under this Section 7.1, the Party and its Affiliates, directors, officers, employees or agents seeking indemnification (an "Indemnified Party") shall promptly notify the other Party (the "Indemnifying Party"), in writing, of any claim asserted or threatened against such Indemnified Party for which such Indemnified Party is entitled to indemnification hereunder from the Indemnifying Party. With respect to any such claim the Indemnified Party shall, at no out-of-pocket expense to it, reasonably cooperate with and provide such reasonable assistance to such Indemnifying Party as such Indemnifying Party may reasonably request. Such reasonable assistance may include, without limitation, providing copies of all relevant correspondence and other materials that the Indemnifying Party may reasonably request. The obligations of an Indemnifying Party under Sections 7.1.1 and 7.1.2 are conditioned upon the delivery of written notice to the Indemnifying Party of any asserted or threatened claim promptly after the Indemnified Party becomes aware of such claim; provided that the failure of the Indemnified Party to give such notice or any delay thereof shall not affect the Indemnified Party's right to indemnification hereunder, except to the extent that such failure or delay impairs the Indemnifying Party's ability to defend or contest any such claim. The Indemnifying Party shall have the right to assume the defense of any suit or claim for which indemnification is sought with counsel reasonably acceptable to the Indemnified Party. If the Indemnifying Party defends the suit or claim, the Indemnified Party may participate in the defense thereof at its sole cost and expense. An Indemnifying Party may not settle a suit or claim without the consent of the Indemnified Party if (a) such settlement would impose any monetary obligation on the Indemnified Party for which indemnification is not provided hereunder, (b) or require the Indemnified Party to submit to an injunction or otherwise limit the Indemnified Party's rights under this Agreement, or (c) does not include a release of the Indemnified Party

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from all liability arising out of such suit or claim. Any payment made by an Indemnifying Party to settle any such suit or claim shall be at its own cost and expense.

7.1.4 The indemnification provided by this Section 7 shall be the Parties' sole and exclusive remedy in connection with any third party claim.

7.2 Insurance.

At the time of Launch and continuing through the Term of this Agreement, ACCESS shall maintain the following kinds of insurance with the minimum limits set forth below.

| Kind of Insurance | Minimum Limits |
|---|---|
| Commercial General Liability, including Contractual, Completed Operations and Product Liability | \$2,000,000 Per Occurrence \$5,000,000 Aggregate |
| Workers Compensation | Statutory with Employer's Liability of not less than \$1,000,000 Per Accident/Disease |
| Automobile Bodily Injury Liability (including hired automobile and non-ownership Liability) | \$1,000,000 Each Accident Combined Single Limit |

Upon request, ACCESS shall furnish insurance certificates as directed by WYETH, satisfactory in form and substance to WYETH, showing the above coverages, and providing for at least thirty (30) days' prior written notice to WYETH by the insurance company of cancellation or modification. WYETH shall be named as an additional insured on the ACCESS's policies. Coverage shall be procured with carriers having an A.M. Best rating of A-VII or better.

8. TERM AND TERMINATION

8.1 Term.

This Agreement shall commence on the Effective Date and continue, unless sooner terminated as set forth below in this Article 8 or as otherwise specifically stated in this Agreement, for the duration of the Term.

8.2 Termination Without Cause.

WYETH may terminate this Agreement at any time (a) after Launch by giving twelve (12) months prior written notice to ACCESS if WYETH, in its sole discretion, determines to cease marketing the Product, or (b) prior to Launch by giving thirty (30) days prior written notice to ACCESS if WYETH, in its sole discretion, determines not to Launch the Product. If

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WYETH terminates this Agreement pursuant to subsection (a) above, WYETH is not obligated to transfer to ACCESS any data relating to the Product (including, without limitation, marketing studies or otherwise) that WYETH generated prior to such termination. If WYETH terminates this Agreement pursuant to subsection (b) above, then, subject to the exceptions set forth in Section 8.3, WYETH shall transfer to ACCESS any data relating solely to the Product that WYETH generated, excluding any NDAs.

8.3 Pre-Launch Termination.

In the event that, prior to Launch, WYETH terminates this Agreement in accordance with Section 8.2(b) above, and such termination is for any of the following reasons, then WYETH shall have no obligation to provide to ACCESS any data relating to the Product (including, without limitation, marketing studies or otherwise) that WYETH generated prior to such termination: (a) ACCESS fails to provide an approvable Third Party manufacturer of the Product in accordance with Section 2.9, (b) WYETH and ACCESS are unable to mutually agree upon a final development plan (including, without limitation, exhibits setting forth the Methods of Analysis and Specifications), as described in Section 2.10, in a timely manner, (c) WYETH and ACCESS are unable to mutually agree upon a final Exhibit E (Prices) in a timely manner, (d) consumer use testing of the Product generates negative reactions from consumers, (e) the cost of purchasing and marketing the Product relative to the effective retail price of the

Product makes the sale of the Product, in WYETH's sole determination, not viable, (f) the stages of a mutually agreed upon development plan are not completed in accordance with Section 2.10 (through no fault of WYETH), (g) breach of the Agreement, or (h) ACCESS fails to complete and validate Manufacturing process, scale up and all other obligations set forth in Section 2.11.

8.4 Termination for Regulatory Action or Claim of Infringement.

WYETH may terminate this Agreement in its entirety immediately if the FDA or any other Regulatory Authority takes any action, the result of which is to prohibit or permanently or otherwise restrict the Manufacture, storage, importation, sale, offer for sale or use of the Product in any way that will have a material, adverse effect on the sale price or sales volumes of the Product, or if any claim is made that the Manufacture, storage, importation, sale, offer for sale or use of the Product infringes any patent or other proprietary or protected right of any Third Party.

8.5 Termination for Breach.

If either Party shall at any time fail to discharge any of its obligations hereunder and shall fail to correct such default within thirty (30) days after the other Party shall have given written notice to it thereof, the aggrieved Party shall be entitled to notify the other Party that it intends to terminate this Agreement unless such default is corrected and may so terminate ten (10) days after the end of such thirty (30) day period if such default is continuing; provided that if such default by the other Party shall be a recurring default and the other Party does not reasonably satisfy the aggrieved party that such defaults shall cease to occur, the aggrieved Party shall be entitled to terminate this Agreement upon the occurrence of such default and the other

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Party shall not be entitled to correct such default.

8.6 Termination for Bankruptcy.

If either Party by voluntary or involuntary action goes into liquidation, dissolves or files a petition for bankruptcy or suspension of payments, is adjudicated bankrupt, has a receiver or trustee appointed for its property or estate, becomes insolvent or makes an assignment for the benefit of creditors, the other Party shall be entitled by notice in writing to such Party to terminate this Agreement forthwith.

8.7 Effect of Termination.

Termination or expiration of this Agreement, in whole or in part, shall be without prejudice to the right of either Party to receive all payments accrued and unpaid at the effective date of such termination or expiration, without prejudice to the remedy of either Party in respect to any previous breach of any of the representations, warranties or covenants herein contained and without prejudice to any other provisions hereof which expressly or necessarily call for performance after such termination or expiration.

8.8 WYETH's Rights on Termination.

Upon termination or expiration of this Agreement for any reason, then (a) at WYETH's request, ACCESS shall supply WYETH with its inventory of Materials, Product and/or works-in-progress for the Manufacture, packaging and labeling of Product and WYETH shall pay ACCESS the manufacturing fee for the Product, a prorated portion thereof for work-in-progress commenced against firm orders by WYETH and the cost of Materials; and (b) at WYETH's request, ACCESS shall return to WYETH all retention samples of the Product.

8.9 Survival.

The following provisions shall survive the expiration or termination of this Agreement: Sections 3.4, 3.6, 3.7, 5.5, 5.6, 5.7, 5.8, 5.9, 5.10, 7.1, 8.7, 8.8, 8.9, and 8.10 and Articles 6, 9, 11, 12 and 13.

9. CONFIDENTIALITY

9.1 Nondisclosure Obligation.

Each of ACCESS and WYETH shall use only in accordance with this Agreement and shall not disclose to any Third Party the Confidential Information received by it from the other Party pursuant to this Agreement, without the prior written consent of the other Party. The foregoing obligations shall survive for a period of five (5) years after the termination or expiration of this Agreement. These obligations shall not apply to Confidential Information that: (a) is known by the receiving Party at the time of its receipt, and not through a prior disclosure by the disclosing Party, as documented by business records; (b) is at the time of disclosure or

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thereafter becomes published or otherwise part of the public domain without breach of this Agreement by the receiving Party; (c) is subsequently disclosed to the receiving Party by a Third Party who has the right to make such disclosure; (d) is developed by the receiving Party independently of the Confidential Information received from the disclosing Party and such independent development can be documented by the receiving Party; or (e) is required by law, regulation, rule, act or order of any governmental authority or agency to be disclosed by a Party, provided that notice is promptly delivered to the other Party in order to provide an opportunity to seek a protective order or other similar order with respect to such Confidential Information and thereafter the disclosing Party discloses to the requesting entity only the minimum Confidential Information required to be disclosed in order to comply with the request, whether or not a protective order or other similar order is obtained by the other Party.

9.2 Permitted Disclosures.

Each Party may disclose the other Party's Confidential Information to its employees and Affiliates on a need-to-know basis and to its agents or consultants to the extent required to accomplish the purposes of this Agreement; provided that the recipient Party obtains prior agreement from such agents and consultants to whom disclosure is to be made to hold in confidence and not make use of such Confidential Information for any purpose other than those permitted by this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own to ensure that such employees, agents, consultants, and Affiliates do not disclose or make any unauthorized use of the other Party's Confidential Information.

9.3 Disclosure of Agreement.

Neither ACCESS nor WYETH shall release to any Third Party or publish in any way any non-public information with respect to the terms of this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed, provided that either Party may disclose the terms of this Agreement (a) to the extent required to comply with applicable laws, including, without limitation, the rules and regulations promulgated by the United States Securities and Exchange Commission; provided, further, that prior to making any such disclosure, the Party intending to so disclose the terms of this Agreement shall (i) provide the nondisclosing Party with written notice of the proposed disclosure and an opportunity to review and comment on the intended disclosure which is reasonable under the circumstances and (ii) shall seek confidential treatment for as much of the disclosure as is reasonable under the circumstances, including, without limitation, seeking confidential treatment of any information as may be requested by the other Party; or (b) to one or more Third Parties and/or their advisors in connection with a proposed spin-off, joint venture, divestiture, merger or other similar transaction involving all, or substantially all, of the Product, assets or business of the disclosing Party to which this Agreement relates or to lenders, investment bankers and other financial institutions of its choice solely for purposes of financing the business operations of such Party; provided, further, that either (i) the other Party has consented to such disclosure or (ii) such Third Parties have signed confidentiality

agreements with respect to such information on terms no less restrictive than those contained in this Article 9; or (c) to its legal counsel.

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9.4 Publicity.

All publicity, press releases and other announcements relating to this Agreement or the transactions contemplated hereby shall be reviewed in advance by, and shall be subject to the approval of, both Parties.

10. FORCE MAJEURE

If the Manufacture, production, delivery, acceptance or use of Product specified for delivery under this Agreement or if the performance of any other obligation hereunder is prevented, restricted or interfered with by reason of fires, accidents, explosions, earthquakes, floods, breakdown of plant, embargoes, government ordinances or requirements, civil or military authorities, acts of God or of the public enemy, or other similar causes beyond the reasonable control of the Party whose performance is affected (any of the foregoing a "Force Majeure Event"), then the Party affected, upon giving prompt written notice to the other Party, shall be excused from such performance on a day-for-day basis to the extent of such prevention, restriction, or interference (and the other Party shall likewise be excused from performance of its obligations on a day-for-day basis to the extent such Party's obligations relate to the performance so prevented, restricted or interfered with); provided that the Party so affected shall use commercially reasonable efforts to avoid or remove such causes of non-performance and both Parties shall proceed to perform their obligations with dispatch whenever such causes are removed or cease. If such Force Majeure Event continues for a period of ninety (90) consecutive days or more and as a result either party has been unable to perform its obligations under this Agreement for such ninety (90) day period, the other Party may terminate this Agreement effective immediately, upon delivery of a notice of termination in writing, provided that such event of Force Majeure Event is continuing. If as a result of any Force Majeure Event above, ACCESS is unable to fully supply WYETH's orders hereunder, ACCESS shall allocate all available quantities of Materials and Product to WYETH in the ratio that the quantities ordered by WYETH in the twelve (12) month period immediately preceding such force majeure event bears to ACCESS's requirements for its own use and for supply to Third Parties for that same period; provided that if this Agreement has not been in effect for a full twelve (12) month period, then such shorter period shall be used in lieu of a twelve (12) month period.

11. INTELLECTUAL PROPERTY

11.1 Trademarks; WYETH Intellectual Property.

11.1.1 WYETH may advertise, promote, market and sell the Product either separately or as part of other products under any of its Trademarks and/or trade dress, whether registered or unregistered, in its sole discretion; provided that except as otherwise expressly permitted under Section 2.1.4 with respect to the Mark, WYETH may not use or adopt any ACCESS Trademark or trade dress, or any such item confusingly similar thereto used or intended to be used prior to the first use of such Trademark. ACCESS shall have no right, title or interest in or to any such Trademark or trade dress, and WYETH shall have no right, title or interest in or

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to any such ACCESS Trademark (except for the license to the Mark granted under Section 2.1.4). So long as WYETH or any Affiliate of WYETH shall have any interest in any such Trademark or trade dress, whether registered or unregistered, whether as proprietor, owner, or licensee in any country of the world, ACCESS shall not adopt, use, apply for registration, register or own such Trademark or trade dress, or any such item confusingly similar thereto in any country of the world, or take any action which weakens or undermines WYETH's proprietary rights therein. So long as ACCESS or any Affiliate of ACCESS shall have any interest in any such ACCESS Trademark or trade dress, whether registered or unregistered,

whether as proprietor, owner, or licensee in any country of the world, except as otherwise expressly permitted under Section 2.1.4 with respect to the Mark, WYETH shall not adopt, use, apply for registration, register or own such ACCESS Trademark or trade dress, or any such item confusingly similar thereto in any country of the world, or take any action which weakens or undermines ACCESS's proprietary rights therein.

11.1.2 For the avoidance of doubt, WYETH shall at all times retain sole and exclusive ownership of its intellectual property, including, without limitation, all marketing and sales plans, artwork, formats, equipment, logos, drawings, customer lists, regulatory filings, correspondence with the FDA or any other Regulatory Authority, clinical study data, analytical data, operating procedures and all ordering and sales information.

11.2 Inventions.

11.2.1 Except as otherwise provided for in this Section 11.2, each Party shall own all Inventions made solely by employees of such Party (or Third Parties acting on behalf of such Party) and shall jointly own with the other Party any Invention made jointly by employees of both Parties (or Third Parties on behalf of one or both Parties); provided that such Inventions were made without violation of any term or condition of this Agreement. All determinations of inventorship under this Agreement shall be made in accordance with United States law.

11.2.2 If and to the extent applicable, Inventions Controlled by ACCESS and know-how arising during the Term which relates to the Product and is Controlled by ACCESS shall be automatically included in the Intellectual Property Rights under which WYETH is licensed pursuant to Section 2.1.1 hereof. With respect to any Inventions or know-how Controlled by WYETH specifically relating to the Product, WYETH hereby grants to ACCESS an exclusive (subject to retained rights in WYETH), royalty-free license to use such Invention for the Manufacture of the Product for WYETH in the Territory during the Term.

11.2.3 During the Term of this Agreement both Parties shall require their employees and personnel involved in the performance of its duties under this Agreement to deliver such assignments, confirmations of assignments or other written instruments as are necessary to vest in the respective Party clear and marketable title to the Inventions.

11.2.4 All rights, title and interest in and to the ACCESS Intellectual Property Rights shall remain exclusively owned by ACCESS. The Inventions owned by ACCESS under this Section shall be referred to herein as "ACCESS Inventions".

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11.2.5 All rights, title, and interest in and to know-how, which is developed jointly by the Parties during the Term of this Agreement and related to the Product, its Manufacture and/or use shall be owned jointly by the Parties. All rights, title, and interest in and to any Regulatory Approval the primary responsibility for which is allocated to a particular Party hereunder that is developed or collected solely or jointly by the Parties in the Territory during the Term of this Agreement shall be owned exclusively by such Party.

11.3 Confidentiality of Information related to Intellectual Property.

Any and all information and material, including, without limitation, any and all intellectual property rights therein and thereto, assigned to a Party pursuant to the terms of this Agreement shall constitute Confidential Information of such Party which shall be deemed the Disclosing Party with respect to such Confidential Information.

11.4 Patent Rights to New Inventions.

11.4.1 ACCESS, at its own expense, shall use commercially reasonable efforts to prepare, file, prosecute and maintain

its Intellectual Property Rights in the countries of the Territory.

11.4.2 With respect to any filings after the Effective Date, ACCESS shall give WYETH a reasonable opportunity to review and comment upon the text of such applications in the Territory before filing, shall consult in good faith with WYETH with respect to such applications in the Territory, and shall supply WYETH with a copy of such applications in the Territory as filed, together with notice of its filing date and serial number. ACCESS shall inform WYETH about the status of the prosecution of all patent applications included within the ACCESS Intellectual Property Rights and its Intellectual Property Rights to Inventions and the maintenance of any patents included within the ACCESS Intellectual Property Rights and its Intellectual Property Rights to Inventions in a country in the Territory.

11.4.3 ACCESS shall consult with WYETH and provide WYETH with reasonable opportunity to comment on all correspondence received from and all submissions to be made to any Regulatory Authority in the Territory with respect to any such patent application or patent. ACCESS shall consider in good faith, but will not be bound by, WYETH's suggestions with respect to all submissions in the Territory made to any Regulatory Authority in the Territory with respect to any such patent application or patent.

11.4.4 If ACCESS elects not to file a patent application with respect to its new Inventions or to cease the prosecution and/or maintenance of any Patent under the ACCESS Intellectual Property Rights in a country in the Territory, ACCESS shall provide WYETH with written notice promptly after the decision to not file or continue the prosecution of such patent application or maintenance of such patent.

11.4.5 In such event, ACCESS shall permit WYETH, in WYETH's sole

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discretion, to file a patent application with respect to such Invention or continue prosecution or maintenance of any such Patent under the ACCESS Intellectual Property Right in such country at WYETH's own expense. If WYETH elects to continue such prosecution or maintenance, ACCESS shall execute such documents and perform such acts, at WYETH's expense, as may be reasonably necessary to permit WYETH to file, prosecute or maintain such application or Patent in such country. In such event, WYETH shall own such patent application or Patent filed by WYETH hereunder.

11.4.6 In the event that WYETH continues the prosecution or maintenance of such patent application or Patent pursuant to this Section, WYETH's Royalty obligations hereunder, and this Agreement, shall expire if, and at such time, that such patent application or Patent becomes the only non-expired Patent rights within the Intellectual Property Rights.

11.4.7 (a) The Parties shall mutually agree in good faith on a case-by-case-basis on which of the Parties shall have the first right to prepare, file, prosecute and maintain any jointly owned Invention and patent rights thereon ("Joint Patent Rights") throughout the world as well as on the split of the applicable expenses and costs.

(b) The acting Party shall keep the other Party completely informed during the whole application procedure as well as during the whole patent duration. The acting Party shall provide the other Party advance copies of any official correspondence related to the filing, prosecution and maintenance of such patent filings, and shall provide the other Party a reasonable opportunity to comment on all correspondence received from and all submission to be made to any government patent office or authority with respect to any such patent application or patent, and shall consider in good faith the other Party's suggestions with respect to all submission made to any government office or authority.

(c) If either Party (the "Declining Party") at any time declines to share in the costs of filing, prosecuting and maintaining any such Joint Patent Right, on a country by country basis,

the Declining Party shall provide the other Party (the "Continuing Party") with thirty (30) days prior written notice to such effect, in which event, the Declining Party shall (i) have no responsibility for any expenses incurred in connection with such Joint Patent Right and (ii) if the Continuing Party elects to continue prosecution or maintenance, the Declining Party, upon the Continuing Party's request, shall execute such documents and perform such acts, at the Continuing Party's expense, as may be reasonably necessary (x) to assign to the Continuing Party all of the Declining Party's right, title and interest in and to such Joint Patent Rights and (y) to permit the Continuing Party to file, prosecute and/or maintain such Joint Patent Right.

(d) If WYETH is (i) the sole owner of a Joint Patent Right or (ii) the Continuing Party, such Joint Patent Right shall no longer be considered to be part of the ACCESS Intellectual Property Rights for purposes of this Agreement and thereafter shall be part of WYETH's intellectual property.

(e) If ACCESS is (i) the sole owner of a Joint Patent Right or (ii) is the Continuing Party, such Joint Patent Rights shall no longer be considered to be part of WYETH's

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intellectual property for purposes of this Agreement and thereafter shall be part of the ACCESS Intellectual Property Rights.

11.4.8 Each Party shall, and shall cause its Affiliates, employees, attorneys and agents to, cooperate fully with the other Party and provide all information and data and execute any documents reasonably required or requested in order to allow the other Party to prosecute, file, and maintain patents and patent applications pursuant to this Section 11.4. Neither Party shall require the other Party to make any payment or reimburse for any expenses in connection with such cooperation, provision of information and data and execution of documents.

11.5 Enforcement of Intellectual Property Rights.

11.5.1 If either Party becomes aware of any infringement of any of the Intellectual Property Rights or the Mark, or the validity of any of the Intellectual Property Rights or the Mark is challenged by a Third Party in the Territory, such Party will notify the other Party in writing to that effect. Any such notice shall include, as applicable, evidence to support an allegation of infringement by such Third Party.

11.5.2 ACCESS shall have the first right, but not the obligation, to take action to obtain a discontinuance of infringement or bring suit against a Third Party infringer of Intellectual Property Rights and/or the Mark in the Territory. Such right shall remain in effect until ninety (90) days after the date of notice given under Section 11.5.1. In the event that ACCESS exercises such right, then: (a) ACCESS shall not consent to the entry of any judgment or enter into any settlement with respect to such an action or suit without the prior written consent of WYETH (not to be unreasonably withheld), and (b) ACCESS shall bear all the expenses of any such suit brought by ACCESS claiming infringement of any Intellectual Property Rights and/or the Mark. If, after the expiration of the ninety (90) day period, ACCESS has not obtained, or is not diligently pursuing, a discontinuance of infringement of the Intellectual Property Rights and/or the Mark, filed suit against any such Third Party infringer of the Intellectual Property Rights and/or the Mark, or provided WYETH with information and arguments demonstrating to WYETH's reasonable satisfaction that there is insufficient basis for the allegation of such infringement of the Intellectual Property Rights and/or the Mark, then WYETH shall have the right, but not the obligation, to bring suit against such Third Party infringer of the Intellectual Property Rights and/or the Mark and to join ACCESS as a party plaintiff, provided that WYETH shall bear all the expenses of such suit. In such event, WYETH shall not consent to the entry of any judgment or enter into any settlement with respect to such an action or suit without the prior written consent of ACCESS (which consent shall not unreasonably be withheld) if such judgment or settlement includes a finding or agreement that such Intellectual Property

Right and/or the Mark is invalid or would enjoin or grant other equitable relief against ACCESS.

11.5.3 Each Party shall cooperate (including, without limitation, by executing any documents reasonably required to enable the other Party to initiate such litigation, testifying when requested or providing relevant documents) with the other Party in any suit for infringement of Intellectual Property Rights and/or the Mark brought by the other Party against a

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Third Party in accordance with this Section and shall have the right to consult with the other Party and to participate in and be represented by independent counsel in such litigation at its own expense.

11.5.4 Neither Party shall be required pursuant to this Section 11.5 to undertake any activities, including, without limitation, legal discovery at the request of a Third Party except as may be required by lawful process of a court of competent jurisdiction.

11.5.5 Neither Party shall incur any liability to the other Party as a consequence of any such litigation or any unfavorable decision resulting therefrom, including, without limitation, any decision holding any of the patents within the Intellectual Property Rights invalid or unenforceable.

11.5.6 Any recovery obtained by either Party as a result of any such proceeding against a Third Party infringer shall be allocated as follows: (a) such recovery shall first be used to reimburse each Party for all litigation costs in connection with such litigation paid by that Party; and (b) the Party bringing the action shall receive the remaining portion of such recovery after payment of the amounts specified in clause (a).

11.6 Trademarks.

Subject to the restrictions in Sections 2.1.4 and 11.1, WYETH shall select and own all Trademarks in connection with the marketing, promotion and sale of the Product in the Territory. WYETH hereby grants to ACCESS a limited, non-exclusive, non-transferable, fully paid, royalty free, sublicensable license in and to all WYETH Trademarks and copyrights to be contained in any such labeling for the sole purpose of manufacturing and applying such labels to the Product in the conduct of ACCESS's obligations hereunder; provided, however, that ACCESS agrees to cooperate with and offer reasonable assistance to WYETH in facilitating WYETH's control of the quality of the Product branded with WYETH's trademarks hereunder; but further provided that in no event is ACCESS obligated to provide such cooperation or assistance in any way that will (i) lower the quality of the Product below that which ACCESS deems acceptable for general commercial distribution, (ii) be contrary to or in violation of any regulatory or statutory obligations, or (iii) increase the cost of manufacturing and delivering the Product hereunder beyond that contemplated by the parties as of the Effective Date.

11.7 Publications.

11.7.1 The Parties recognize that limited rights of review and/or comment exist for certain Third Party publications, such as medical, academic and scientific publications. Each Party agrees to provide the other Party with any such proposed publication or presentation promptly upon its receipt. Each Party may advise the other of any comments that it may have relating to such proposed publication or presentation and do so within the applicable time frame.

11.7.2 During the Term of this Agreement, unless otherwise prohibited by law, each Party shall submit to the other Party for review and approval any proposed publication or

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public presentation, especially including, without limitation, academic, scientific and medical information, which contains the non-disclosing

Party's Confidential Information or which disclose any non-public information contained within the Intellectual Property Rights or which makes any reference to the subject matter of this Agreement or the Product.

11.7.3 Written copies of each such proposed publication or presentation required to be submitted hereunder shall be submitted to the non-disclosing Party no later than fifteen (15) days before its intended submission for publication or presentation. The non-disclosing Party shall provide its comments with respect to such publications and presentations within ten (10) business days of its receipt of such written copy. The review period may be extended for an additional thirty (30) days in the event the non-disclosing Party can demonstrate reasonable need for such extension. By mutual agreement of the Parties in writing, this period may be further extended.

11.7.4 The Parties acknowledge that as publicly held corporations, the Parties may not lawfully disclose in advance certain information to any party, including, without limitation, the other Party. This may affect the Parties' ability to submit for review certain proposed publications and public presentations.

11.7.5 Regarding their publications under this Section 11.7, ACCESS and WYETH will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication.

12. NOTICES

12.1 Ordinary Notices.

Correspondence, reports, documentation, and any other communication in writing between the Parties in the course of ordinary implementation of this Agreement shall be delivered by hand, sent by facsimile or by overnight courier to the employee or representative of the other Party who is designated by such other Party to receive such written communication at the address or facsimile numbers specified by such employee or representative.

12.2 Extraordinary Notices.

Extraordinary notices and communications (including, without limitation, notices of termination, Force Majeure Event, material breach, change of address, requests for disclosure of Confidential Information, claims or indemnification) shall be in writing and shall be delivered by hand, sent by facsimile or by overnight courier (and shall be deemed to have been properly served to the addressee upon receipt of such written communication) to the address set forth in Section 12.3 or such other address as notified in writing by such Party to the other Party.

12.3 Addresses.

If to WYETH:

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Wyeth Consumer Healthcare, a division of Wyeth
Five Giralda Farms
Madison, New Jersey 07940
Attention: Associate Director of Contract Manufacturing
Facsimile No.: 973-660-7325

With a copy to:

Wyeth
Five Giralda Farms
Madison, New Jersey 07940
Attention: General Counsel
Facsimile No.: 973-660-7050

If to ACCESS:

Access Pharmaceuticals, Inc.
2600 Stemmons Freeway
Suite 176

Dallas, Texas 75207-2107
Attention: President
Facsimile No.: 214-905-5101

With a copy to:

John J. Concannon, Esq.
Bingham McCutchen LLP
150 Federal Street
Boston, MA 02110
Facsimile No.: 617-951-8736

13. GENERAL

13.1 Governing Law.

This Agreement shall be construed in accordance with and governed by the law of the State of New York, without giving effect to its conflict of laws provisions, and to the exclusion of the provisions of the United Nations Convention on Contracts for the International Sale of Goods.

13.2 Equal Opportunity Clause.

The Equal Opportunity Clause required by Executive Orders 11246, as amended (41-CFR 60-1.4) and 11375, the Employment Assistance to Veterans Clause required by

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Executive Order 11701 (41CFR 60-250.4), the Vietnam Era Veteran Readjustment Act of 1972, the Employment of the Handicapped Clause required by the Rehabilitation Act of 1973 (41 CFR 60-741.4) and the Americans with Disabilities Act of 1991 are part of this Agreement and binding upon ACCESS unless exempted by rules, regulations or orders of the Secretary of Labor. ACCESS agrees that the applicable clause with regard to the utilization of minority contractors set forth at 41 CFR 1-1.303 and the applicable clause with regard to the Utilization of Small Business Concerns and Small Business Concerns Owned and Controlled by Socially and Economically Disadvantaged Individuals set forth at 41 CFR 1-1.13 are incorporated herein by reference, as applicable. ACCESS agrees to provide information and documentation with respect to the foregoing to WYETH upon request.

13.3 Assignment.

This Agreement shall not be assignable or transferable by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided that either Party may assign this Agreement and its rights and obligations hereunder without the other Party's consent in connection with the transfer or sale of all or substantially all of the business of such party to which this Agreement relates (or, if applicable, the business unit or division of such Party primarily responsible for performance under this Agreement) to another party, whether by merger, sale of stock, sale of assets or otherwise; and provided further that in the event any NDA has been filed with respect to the Product, WYETH shall have the right to assign or sublicense this Agreement and its rights and obligations hereunder without ACCESS's consent. In the event that WYETH sublicenses the Agreement or any rights or obligations hereunder in accordance with the previous sentence, then WYETH shall guaranty the performance of the sublicensee. In the event that either WYETH or ACCESS assigns this Agreement in accordance with this Section 13.3, then the assigning Party shall be released from its obligations hereunder and shall have no further obligations to the other Party pursuant to this Agreement. The rights and obligations of the parties under this Agreement shall be binding upon and inure to the benefit of the successors and permitted assigns of the parties. Any attempted assignment in violation of this Section 13.3 shall be null and void, without any force or effect.

13.4 Entire Agreement.

This Agreement and all Exhibits attached hereto (as the

same may be amended from time to time by the written agreement of the Parties) constitute the entire agreement between the Parties with respect to the subject matter hereof and supersedes all other documents, agreements, verbal consents, arrangements and understandings between the Parties with respect to the subject matter hereof. This Agreement shall not be amended orally, but only by an agreement in writing, signed by both Parties that states that it is an amendment to this Agreement.

13.5 Severability.

If any term of this Agreement shall be found to be invalid, illegal or unenforceable, it is the intention of the parties that the remainder of this Agreement shall not be

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affected thereby; provided that neither Party's rights under this Agreement are materially adversely affected. It is further the intention of the parties that in lieu of each such provision which is invalid, illegal or unenforceable, there be substituted or added as part of this Agreement a provision which shall be as similar as possible in the economic and business objectives intended by the Parties to such invalid, illegal or unenforceable provision, but which shall be valid, legal and enforceable. In the event that either Party's rights are materially adversely affected as a result of a change in this Agreement as contemplated by this Section, such Party may terminate this Agreement by notice in writing to the other Party given no later than sixty (60) days after such change.

13.6 Independent Contractor.

Each Party shall act as an independent contractor and neither Party shall have any authority to represent or bind the other Party in any way.

13.7 No Waiver.

Any waiver by one Party of any right of such Party or obligation of the other Party must be in writing and shall not operate as a waiver of any subsequent right or obligation.

13.8 Counterparts.

This Agreement may be executed in two or more counterparts (including, without limitation, by facsimile transmission), each of which when so executed and delivered shall be an original, but all of which together shall constitute one and the same instrument.

13.9 HSR Compliance.

Within 15 business days after signing, WYETH will value ACCESS's grant of the exclusive license contemplated by this License and Supply Agreement in compliance with Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, 15 U.S.C % 18a, and the regulations promulgated thereunder, 16 C.F.R %% 801.1 et seq. ("the Act") and will notify ACCESS whether a Notification and Report Form is required under the Act based upon such valuation. If an HSR filing is required, the parties will, at their own expense, prepare and make appropriate filings under the Act as soon as reasonably practicable after WYETH's notice. The parties agree to cooperate in the antitrust clearance process and agree to furnish promptly to the Federal Trade Commission and/or the Antitrust Division of the Department of Justice any additional information reasonably requested by them in connection with such filings. In the event that the waiting period provided under the Act does not occur within three (3) months after the date of signature of the this Agreement by both parties, the parties shall revert to their status prior to signing the Agreement.

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IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

WYETH, acting through its
Wyeth Consumer Healthcare

Division

By: /s/ Valerie J. Caruso
Name: Valerie J. Caruso
Title: Sr. Vice President

ACCESS PHARMACEUTICALS, INC.

By: /s/ Kerry P. Gray
Name: Kerry P. Gray
Title: President & CEO

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: May 17, 2004

/s/ Kerry P. Gray

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: May 17, 2004

/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 March 31, 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 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 17th day of May, 2004.

/s/ Kerry P. Gray

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 March 31, 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 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 17th day of May, 2004.

/s/ Stephen B. Thompson

Stephen B. Thompson
Chief Financial Officer