

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 SEPTEMBER 30, 2005

Commission File Number 0-9314

ACCESS PHARMACEUTICALS, INC.

-----  
(Exact name of registrant as specified in its charter)

Delaware

83-0221517

-----  
(State of Incorporation)

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

2600 Stemmons Frwy, Suite 176, Dallas, TX 75207

-----  
(Address of principal executive offices)

Telephone Number (214) 905-5100

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

Yes  No

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

Yes  No

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchanges Act)

Yes No

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The number of shares outstanding of the issuer's common stock, as of November 14, 2005, was 17,630,040 shares, \$0.01 par value per share.

Total No. of Pages 43  
ACCESS PHARMACEUTICALS, INC.

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## PART I -- FINANCIAL INFORMATION

### Business

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Access Pharmaceuticals, Inc. (Access) is a Delaware corporation. We are an emerging pharmaceutical company developing unique polymer linked cytotoxics for use in the treatment of cancer. Our lead product AP5346 is in Phase II clinical testing. The Company also has other advanced drug delivery technologies including vitamin-mediated targeted delivery and oral care drug delivery.

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

- \* synthetic polymer targeted delivery,
- \* vitamin mediated targeted delivery
- \* vitamin mediated oral delivery, and
- \* mucoadhesive liquid technology.

### Recent Developments

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We began an asset sale process in the third quarter of 2005 as a way to properly maximize the potential of all the technologies in our patent portfolio. Following the receipt of offers, a decision was made to sell our oral care business to Uluru, Inc., a private Delaware company, for up to \$20.6 million. This transaction closed on October 12, 2005. This includes our interest in Aphthasol(R), all OraDisc(TM) products, all Residerm(R) products, and all of our assets related to these products. In addition, we have licensed to Uluru our nanoparticle hydrogel aggregate technology which could be used for applications such as local drug delivery and tissue filler in dental and soft tissue applications. The CEO of Uluru is Kerry P. Gray, the former CEO of Access

Pharmaceuticals, Inc. In conjunction with the sale transaction, we received a fairness opinion from a nationally recognized investment banking firm.

Uluru assumed eight employees from the Company and six employees remained with Access. Throughout the transition period until Uluru relocates to a new space, leasing arrangements will be cost shared.

At the closing of this agreement we received \$8.7 million. In addition, at the one year anniversary of the agreement we may receive up to \$3.7 million, and we will receive an additional \$1 million within 24 months after closing or earlier upon the achievement of a milestone. Additional payments of up to \$7.2 million may be made upon the achievement of certain additional milestones.

The upfront payment of this transaction allowed Access to immediately retire our \$2.6 million of Secured Convertible Notes held by Cornell Capital and its affiliate and the various agreements relating to these notes. Such notes were secured by all of our assets. In addition, the elimination of the manufacturing and regulatory costs associated with the oral care business, as well as required employees for these marketed products and product candidates will allow us to reduce our burn rate substantially.

On Nov. 9, 2005 we announced the restructuring and repayment of our 7.0% convertible promissory notes due September 13, 2005.

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One holder of \$4 million worth of convertible notes (Oracle Partners LP and related funds) agreed to amend their notes to a new maturity date, April 28, 2007, with the conversion price being reduced from \$5.50 per share to \$1.00 per share. In addition, the Company may cause a mandatory conversion of the notes into common stock if the Company's stock trades at a price of at least 1.5 times the conversion price for a minimum number of trading days. There is also a provision to allow for a minimum price for conversion in the event of a change of control.

The Company was unable to reach a conversion agreement with the second holder of \$4 million worth of notes (Philip D. Kaltenbacher), and has instead settled his claim by paying him this amount plus expenses and interest as outlined in the terms of the note.

While these transactions place the Company in a stronger financial position, the board of directors and senior management are continuing to explore strategic options for the Company to support the continuation of our oncology programs. Options still under consideration include equity financing, out-licensing of technologies and development programs, a joint venture or other strategic alternatives. We have engaged an investment bank to assist us in the exploration of these options.

We remain listed on AMEX but we will need to meet the continuing listing requirements of AMEX by December 31, 2005.

#### Other Key Developments

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On May 11, 2005, we announced that Kerry P. Gray resigned as our President and Chief Executive Officer, effective as of May 10, 2005. Mr. Gray resigned from our Board of Directors and from all other positions held with us, effective as of May 10, 2005. We entered into a Separation Agreement with Mr. Gray dated as of May 10, 2005. Pursuant to the terms of the Separation Agreement, Mr. Gray agreed to provide us with certain post-termination assistance. He also agreed to maintain the confidentiality of our proprietary information and to a

customary mutual release of claims with us. The Separation Agreement provides for an immediate cash payment to Mr. Gray of \$225,000 and payments of \$33,333.33 each month for a period of 18 months, which payments are secured by a lien on our assets. We are required to issue 3,500 shares of our common stock to Mr. Gray each month for a period of 18 months following May 10, 2005. The Separation Agreement also provides that all of Mr. Gray's outstanding stock options and shares of restricted stock immediately and fully vested and options remain exercisable for a period of two years.

On May 11, 2005, we announced that Rosemary Mazanet, M.D., Ph.D., had been named by the Board of Directors as our Acting Chief Executive Officer, effective as of May 11, 2005. The agreement is memorialized in a Letter Agreement with us, dated May 10, 2005. Dr. Mazanet's title will be Acting Chief Executive Officer and she will report directly to, and be subject to the direction of, our Board of Directors.

As of March 30, 2005 the Company executed a Standby Equity Distribution Agreement (SEDA) with Cornell Capital Partners. Under the SEDA, the Company may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to \$15,000,000. The purchase price for the shares is equal to their market price, which is defined in the SEDA as 98% of the lowest volume weighted average price of the common stock during a specified period of trading

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days following the date notice is given by the Company that it desires to access the SEDA. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we receive under the Equity Line of Credit. The amount of each draw down is subject to a maximum amount of \$1,000,000. The terms of the SEDA do not allow us to make draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our outstanding shares of common stock. Upon closing of the transaction, Cornell Capital Partners received a one-time commitment fee of 146,500 shares of the Company's common stock. On the same date, the Company entered into a Placement Agent Agreement with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the Placement Agent Agreement, upon closing of the transaction the Company paid a one-time placement agent fee of 3,500 shares of common stock. As of September 30, 2005 we have accessed \$600,000 of the SEDA. At this time the Company will not be able to access the SEDA until a post-effective amendment to our registration statement is filed with, and declared effective by, the SEC.

In addition, as of March 30, 2005, the Company executed a Securities Purchase Agreement with Cornell Capital Partners and Highgate House Funds. Under the Securities Purchase Agreement, upon closing Cornell Capital Partners and Highgate House Funds purchased an aggregate of \$2,633,000 principal amount of Secured Convertible Debentures from the Company (net proceeds to the Company of \$2,360,000). The Secured Convertible Debentures accrue interest at a rate of 7% per year and were to mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the Secured Convertible Debenture has not been converted to common stock. The Secured Convertible Debenture was convertible into the Company's common stock at the holder's option any time up to maturity at a conversion price equal to \$4.00. The Secured Convertible Debentures were secured by all of the assets of the Company. The Company had the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, the Company had required to issue to the holders an aggregate of 50,000 shares of common stock of the Company. The Secured Convertible Notes were paid in full on October 12, 2005 in conjunction with the sale of our oral care assets.

We were founded in Wyoming in 1974 as Chemex Corporation, and

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

#### Products

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

#### Products in Development Status

##### Polymer Platinite

Chemotherapy, surgery and radiation are the major components in the clinical management of cancer patients. Chemotherapy is usually the primary treatment of hematologic malignancies, which cannot be excised by surgery. Chemotherapy is increasingly used as an adjunct to radiation

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and surgery to improve their effectiveness and serves as the primary therapy for some solid tumors and metastases. For chemotherapeutic agents to be effective in treating cancer patients, however, the agent must reach the target cells in effective quantities with minimal toxicity in normal tissues.

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

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

##### Polymer Platinite (AP 5346) DACH Platinum

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

Oxaliplatin, another form of DACH platinum, which was initially approved in France and in Europe in 1999 for the treatment of colorectal cancer is now also being marketed in the United States and is generating worldwide sales in excess of \$1.5 billion annually. Carboplatin and Cisplatin, two approved platinum chemotherapy drugs, are not indicated for the

treatment of metastatic colorectal cancer. Oxaliplatin, in combination with 5-fluorouracil and folinic acid is indicated for the first-line treatment of metastatic colorectal cancer in Europe and the U.S. The colorectal cancer market is a significant opportunity as there are over 500,000 reported new cases annually in the developed world, increasing at a rate of approximately three percent per year.

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

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tumors. An extensive preclinical package has been developed supporting the development of AP5346.

In the first quarter of 2005, we completed a Phase I clinical study in a multi-center study conducted in Europe, enrolling approximately 26 patients. The reporting of this study is expected to be completed in the fourth quarter of 2005. The European trial was designed to identify the maximum tolerated dose, dose limiting toxicities, the pharmacokinetics of the platinum in plasma and the possible antitumor activity of AP5346. The open-label, non-randomized, dose-escalation Phase I study was performed at two European centers. AP5346 was administered as an intravenous infusion over one hour, once a week on days 1, 8 and 15 of each 28-day cycle to patients with solid progressive tumors. We have obtained preliminary reports on results in 26 patients with a broad cross-section of tumor types, with doses ranging from 80-1,280 mg Pt/m<sup>2</sup>.

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

We will be presenting data from this completed Phase I trial of our lead oncology product AP5346 at the AACR-NCI-EORTC international conference on Molecular Targets and Cancer Therapeutics, held in Philadelphia on Nov 16, 2005.

In the current quarter, we plan to begin a European phase II trial in ovarian cancer patients who have relapsed after first line platinum therapy.

We received clearance in January 2005 from the US Food and Drug Administration for our Investigational New Drug Application

(IND) for AP5346 allowing us to proceed with a Phase I clinical trial for this drug candidate in the US. Although we ultimately plan to study AP5346 in combination with fluorouracil and leucovorin, we are choosing to pursue a monotherapy evaluation first. Upon a successful completion of the phase II ovarian study, we plan to initiate a Phase II study to determine the efficacy of AP5346 in combination with fluorouracil and leucovorin in colorectal cancer patients compared with the oxaliplatin/fluorouracil/leucovorin combination, which is used extensively to treat colorectal cancer.

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

The same polymer backbone platform that we use in AP5346 can be used with other anticancer agents, and we have some exciting preclinical data demonstrating the enhancement of efficacy by using the polymer delivery approach. We will be evaluating which of these programs will continue to preclinical candidate formal testing.

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### Nanoparticle drug delivery system

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We also plan to continue to explore collaborations for our proprietary nanoparticle drug delivery system for targeting therapeutics in diseases such as cancer and possibly also rheumatoid arthritis. This nanoparticle drug delivery technology allows for systemic delivery and is different from the aggregate hydrogel that has been licensed to Uluru. There has been increased interest in the use of nanoparticles for delivering drugs to tumors following the approval earlier this year of a taxol nanoparticle formulation. Access' proprietary vitamin-targeting technology is another mechanism to provide enhanced delivery of nanoparticle formulations to the sites of disease. Our vitamin B12 oral drug delivery technology also offers great promise to provide oral dosage forms for active ingredients such as proteins and peptides which currently can only be administered by injection. Access already has three ongoing collaborations in this area, and is currently in discussion with additional potential partners. The level of activity for this program will depend on raising additional financing or executing an outlicensing strategy.

### Mucoadhesive Liquid Technology (MLT)

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

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

In July 2001, we announced results from our Phase II randomized

clinical study of the prevention and treatment of mucositis. The data developed confirmed that our mucoadhesive liquid technology (MLT) could represent an important advancement in the management and prevention of mucositis.

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

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

Given the results achieved with our MLT, and the fact that in the study an amlexanox rinse showed no additional benefit, we do not plan to conduct additional clinical studies evaluating amlexanox as a preventative product candidate for mucositis. Following the completion of the

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Phase II study we conducted additional formulation development work to optimize the MLT technology prior to advancing clinical development. The topical application of the MLT was tested for its ability to attenuate the course of radiation-induced oral mucositis in an established hamster model. The study results clearly indicate the ability to prevent the onset of ulcerative mucositis, or delay the onset and reduce the severity of mucositis. Further clinical development of this program has been placed on hold to focus our resources on our high potential cancer therapeutics. Further development will be dependent on securing a strategic partner.

#### Drug Development Strategy

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

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

Consequently, we expect to form strategic alliances for product development and to outlicense the commercial rights to



development partners. By forming strategic alliances with major pharmaceutical and diagnostic companies, we believe that our technology can be more rapidly developed and successfully introduced into the marketplace.

#### Core Drug Delivery Technology Platforms

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

- \* Synthetic Polymer Targeted Drug Delivery Technology;
- \* Vitamin Mediated Targeted Delivery Technology;
- \* Vitamin Mediated Oral Delivery Technology;
- \* Bioerodible Cross-Linker Technology;

Each of these platforms is discussed below:

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#### Synthetic Polymer Targeted Drug Delivery Technology

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

#### Vitamin Mediated Targeted Delivery Technology

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

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

malignant cells thus reducing damage to collateral tissues.

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

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

\* passive tumor targeting involves transporting anti-cancer agents through the bloodstream to tumor cells using a "carrier" molecule. Many different carrier molecules, which can

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take a variety of forms (micelles, nanoparticles, liposomes and polymers), are being investigated as each provides advantages such as specificity and protection of the anti-cancer drug from degradation due to their structure, size (molecular weights) and particular interactions with tumor cells. Our polymer platinate program is a passive tumor targeting technology.

\* active tumor targeting involves attaching an additional fragment to the anticancer drug and the carrier molecule to create a new "targeted" agent that will actively seek a complementary surface molecule to which it binds (preferentially located on the exterior of the tumor cells). The theory is that the targeting of the anti-cancer agent through active means to the affected cells should allow more of the anti-cancer drug to enter the tumor cell, thus amplifying the response to the treatment and reducing the toxic effect on bystander, normal tissue.

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

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

#### Vitamin Mediated Oral Delivery Technology

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

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

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

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

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

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

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

#### Bioerodible Cross-Linker Delivery Technology

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Our scientists have developed a novel series of bioerodible cross-linkers that have the potential to be utilized with hydrogels in a number of drug delivery applications as well as several non-pharmaceutical applications. Hydrogels are very large molecules with complex three-dimensional structures capable of storing either small molecule drugs or much larger peptide and protein therapeutics. These molecules are stored within the matrix of the hydrogel. Most hydrogels are not bioerodible, therefore they deliver their payload of drug by diffusion of these molecules through the interconnecting chambers of the hydrogel. Once all of the drug has been delivered, non-bioerodible hydrogels remain in the body (unless surgically removed) as they cannot be broken down and

eliminated. By comparison, our hydrogels possess bioerodible linking groups with well-defined rates of degradation in biological systems, and so release their payload of drugs by both diffusion and erosion of the hydrogel matrix. By selecting linkers with appropriate degradation rates, much greater control of drug release rates can be achieved. Once the drug has been released, erosion of the hydrogel continues until no solid hydrogel remains, eliminating the need to use an additional procedure to remove the drug delivery device. The hydrogel erodes to form much smaller water-soluble fractions which are readily eliminated from the body.

A number of possible drug delivery systems may be able to be developed using our bioerodible cross-linker technology, ranging from nanoparticles for intravenous administration, to larger devices which may be implanted, wound packaging materials, medicated and non-medicated for

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decubitus and vascular ulcers, medicated films and gels for topical applications, burn dressing and dressing for skin donor sites.

Research Projects, Products and Products in Development

ACCESS DRUG PORTFOLIO

<TABLE>

<CAPTION>

Compound	Licensing		Clinical		
	Originator	Partner	Indication	FDA Filing	Stage (1)
<S> Cancer	<C>	<C>	<C>	<C>	<C>
Polymer Platinate (AP5346) (2)	Access - U London	-	Ovarian, Colorectal	Clinical Development	Phase I/II

Vitamin Medicated Delivery

Oral Delivery System    Access    -(4) Various    Research    Pre-Clinical

Vitamin Targeted Therapeutics    Access    -    Anti-tumor    Research    Pre-Clinical

</TABLE>

- (1) For more information, see "Government Regulation" for description of clinical stages.
- (2) Licensed from the School of Pharmacy, The University of London. Subject to royalty and milestone payments.
- (3) Clinical studies being conducted in Europe and US.
- (4) Research collaboration agreement with Celltech Group plc.

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

Once the product candidate has been successfully screened in pilot testing, our scientists, together with external consultants, assist in designing and performing the necessary preclinical efficacy, pharmacokinetic and toxicology studies required for IND submission. External investigators and scaleup manufacturing facilities are selected in conjunction with our

consultants. The initial Phase I and Phase II studies are conducted by institutions and investigators supervised and monitored by our employees and contract research organizations. We do not plan to have an extensive clinical development organization as we plan to have the advance phases of this process conducted by a development partner. Should we conduct Phase III clinical studies we expect to engage a contract research organization to perform this work.

We contract with third party contract research organizations to complete our large clinical trials and for data management of all of our clinical trials. Generally, we manage the smaller Phase I

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and II trials ourselves. Currently, we have one Phase I trials in process, one planned Phase I trials and two Phase II trials planned for this year, subject to financing.

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

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

Patents

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

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

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

We have filed two U.S. patent applications and two European

patent applications for our mucoadhesive liquid technology. Our patent applications cover a range of products utilizing our mucoadhesive liquid technology for the management of the various phases of mucositis.

We have three patented targeted therapeutic technologies:

- - folate conjugates of polymer therapeutics, to enhance tumor delivery by targeting folate receptors, which are upregulated in certain tumor types with two U.S. and two European patent applications;

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- - the use of vitamin B12 to target the transcobalamin II receptor which is upregulated in numerous diseases including cancer, rheumatoid arthritis, certain neurological and autoimmune disorders with two U.S. patents and three U.S. and four European patent applications; and

- - oral delivery of a wide variety of molecules which cannot otherwise be orally administered, utilizing the active transport mechanism which transports vitamin B12 into the systemic circulation with six U.S. patents and two European patents and one U.S. and one European patent application.

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

#### Government Regulation

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

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

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

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

Preclinical tests are conducted in the laboratory, usually involving animals, to evaluate the safety and efficacy of the potential product. The results of preclinical tests are submitted as part of the IND application and are fully reviewed by the FDA prior to granting the sponsor permission to commence clinical trials in humans. All trials are conducted under

International Conference on Harmonization, or ICH, good clinical practice guidelines. All investigator sites and sponsor facilities are subject to FDA inspection to insure compliance. Clinical trials typically involve a three-phase process. Phase I, the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages and in some indications such as cancer and HIV, as

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preliminary evidence of efficacy in humans. Phase II involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. When a product is found safe, an initial efficacy is established in Phase II, it is then evaluated in Phase III clinical trials. Phase III trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit to risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA for approval to commence commercial sales.

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

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

#### Competition

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The pharmaceutical and biotechnology industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and other product areas where we may develop and market products in the future. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technical resources than are available to us. Additionally, many of our potential competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our product lines. Our potential products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be addressed by our developments, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our potential competitors. Our business, financial condition and results of operation could be materially adversely affected by any one or more of such developments. We cannot assure you that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operations. Academic institutions, governmental agencies and other public and private research organizations are also conducting research activities and seeking patent protection and may commercialize products on their own or with the assistance of major health care companies in areas where we are developing product candidates. We are aware of certain development projects for products to treat or prevent certain diseases targeted by us, the existence of these potential products or other products or treatments of which we are not aware, or products or treatments that may be developed in the future, may adversely affect the

marketability of products developed by us.

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

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system with a favorable pharmacokinetic profile.

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

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

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

#### Employees

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As of November 14, 2005, we had five full time employees, three of whom have advanced scientific degrees. We have never experienced employment-related work stoppages and consider that we maintain good relations with our personnel. In addition, to complement our internal expertise, we have contracts with scientific consultants, contract research organizations and university research laboratories that specialize in various aspects of drug development including clinical development, regulatory affairs, toxicology, process scale-up and preclinical testing.

#### Web Availability

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We make available free of charge through our web site, [www.accesspharma.com](http://www.accesspharma.com), our annual reports on Form 10-K and other reports required under the Securities and Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are filed with, or furnished to, the Securities and Exchange Commission as well as certain of our corporate governance policies, including the charters for the Board of Director's audit, compensation and nominating and corporate governance committees and our code of ethics, corporate



governance guidelines and whistleblower policy. We will provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207 attn: Investor Relations.

#### Risk Factors

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This Quarterly Report on Form 10-Q contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, and that involve risks and uncertainties, including, but not limited to the uncertainties associated with research and development

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activities, clinical trials, our ability to raise capital, our ability to repay our outstanding debt obligations, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations, future cash flow, the timing and receipt of licensing and milestone revenues, the future success of our marketed products and products in development, our ability to achieve licensing milestones and other risks described below as well as those discussed elsewhere in this Form 10-Q, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission. Forward-looking statements contained in this Form 10-Q include, but are not limited to those relating to anticipated product approvals and timing thereof, the terms of future licensing arrangements, our ability to secure additional financing for our operations, our ability to repay our outstanding debt obligations, our ability to fund our operations through January 31, 2006 with our current cash reserves and without accessing our SEDA, and our expected capital expenditures.

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

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We currently have liquid assets to allow us to continue operations through January 31, 2006, assuming no receipt of funds from any financing transactions, including selling equity securities in connection with our Standby Equity Distribution Agreement (the "SEDA") with Cornell Capital. We anticipate that we will be able to raise additional funds by selling equity securities in connection with our SEDA with Cornell Capital, subject to the terms of the SEDA, our ability to adhere to the terms of the SEDA and our ability to file and utilize an updated registration statement necessary for such sales. We also anticipate raising capital from other sources. By selling equity, the relative equity ownership of our existing investors would be diluted and the new investors could obtain terms more favorable than previous investors.

We have limited liquid assets.

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We currently have liquid assets sufficient to fund our operations only through January 31, 2006 without accessing our SEDA or raising other equity capital. We do plan on accessing the SEDA and/or raising other equity capital. If we are unable to access the SEDA or raise other financing prior to the exhaustion of our liquid assets we may be required to cease or curtail our operations.

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

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We have recorded minimal revenue to date and we have incurred a cumulative operating loss of approximately \$72.8 million

through September 30, 2005. Losses for the years ended 2004, 2003 and 2002 were \$10,238,000, \$6,935,000 and \$9,384,000, respectively. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop clinical drug candidates and from the associated administrative costs. We expect to incur additional operating losses over the next several years. We also expect cumulative losses to increase if we expand research and development efforts and preclinical and clinical trials.

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

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To date, we have funded our operations primarily through private sales of common stock and convertible notes. Contract research payments and licensing fees from corporate alliances and mergers have also provided funding for our operations. Our ability to achieve significant revenue

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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 sold our only revenue producing assets to Uluru, Inc. in October 2005. We are not expecting any revenues in the short-term from our other assets. Furthermore, we may not be able to ever successfully identify, develop, commercialize, patent, manufacture, obtain required regulatory approvals and market any additional products. Moreover, even if we do identify, develop, commercialize, patent, manufacture, and obtain required regulatory approvals to market additional products, we may not generate revenues or royalties from commercial sales of these products for a significant number of years, if at all. Therefore, our proposed operations are subject to all the risks inherent in the establishment of a new business enterprise. In the next few years, our revenues may be limited to minimal product sales and royalties, any amounts that we receive under strategic partnerships and research or drug development collaborations that we may establish and, as a result, we may be unable to achieve or maintain profitability in the future or to achieve significant revenues in order to fund our operations.

AMEX listing requirements.

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Our common stock is presently listed on the American Stock Exchange under the symbol "AKC". All companies listed on AMEX are required to comply with certain continued listing standards, including corporate governance requirements, maintaining stockholders' equity at required levels, obtaining shareholder approvals for certain transactions, share price requirements and other rules and regulations of AMEX, some of which requirements we are not currently in compliance with. AMEX listing requirements allow us to issue a maximum aggregate of 3,089,422 shares of our Common Stock in connection with SEDA without receipt of shareholder approval. Any issuances above such amount would require shareholder approval or would be a violation of AMEX regulations. We are not in compliance with the AMEX stockholders' equity standard as of September 30, 2005. However, we have until December 31, 2005 to become compliant with such equity standard. If we are unable to remedy any listing standard noncompliance with AMEX under its regulations, or otherwise regain compliance, and within the required time frames for such remediation, or otherwise regain compliance, or if we default on our debt obligations we cannot assure investors that our common stock will continue to remain eligible for listing on AMEX. In the event that our common stock is delisted from AMEX its market value and liquidity could be materially adversely affected.

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

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We are dependent on external financing to fund our operations. Our financial needs may be partially provided from the SEDA. The issuance of shares of our common stock under the SEDA will have a dilutive impact on our other stockholders and the issuance or even potential issuance of such shares could have a negative effect on the market price of our common stock. In addition, if we access the SEDA, we will issue shares of our common stock to Cornell Capital Partners at a discount to the lowest daily volume weighted average of our common stock during a specified period of trading days after we access the SEDA. Issuing shares at a discount will further dilute the interests of other stockholders and may negatively affect the market price of our Common Stock.

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

At this time we are not be able to draw funds from the SEDA until an amendment to our registration statement relating to the SEDA is filed and declared effective by the SEC.

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

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We may not generate the cash flow required to pay our liabilities as they become due. Our outstanding debt includes approximately \$9.515 million of our Convertible Subordinated Notes \$4.015 million due in April 2007 and \$5.5 million due in September 2010.

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

We may be unable to repay or repurchase or restructure the convertible subordinated notes due in April 2007 and September 2010 and be forced into bankruptcy. In the event of a default, the holders of our secured convertible notes have the right to foreclose on all of our assets, which could force us to curtail or cease our business operations.

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

We may not successfully commercialize our drug candidates.

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Our drug candidates are subject to the risks of failure inherent in the development of pharmaceutical products based on new technologies and our failure to develop safe, commercially viable drugs would severely limit our ability to become profitable or to achieve significant revenues. We may be unable to successfully commercialize our drug candidates for a number

of reasons, including:

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

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

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

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

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We require substantial capital for our development programs and operating expenses to pursue regulatory clearances and to prosecute and defend our intellectual property rights. We believe that our existing capital resources and interest income will be sufficient to fund our currently expected operating expenses through January 31, 2006. We plan to access our SEDA and/or completing additional financings. We will need to raise substantial additional capital to support our ongoing operations and debt obligations.

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

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

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Our strategy for the research, development and commercialization of our potential pharmaceutical products may require us to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others, in addition to our existing relationships with other parties. Specifically, 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.

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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.

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We have limited experience in the manufacture of pharmaceutical products in clinical quantities or for commercial purposes and we may not be able to manufacture any new pharmaceutical products that we may develop. As a result, we have established, and in the future intend to establish arrangements with contract manufacturers to supply sufficient quantities of products to conduct clinical trials and for the manufacture, packaging, labeling and distribution of finished pharmaceutical products if any of our potential products are approved for commercialization. If we are unable to contract for a sufficient supply of our potential pharmaceutical products on acceptable terms, our preclinical and human clinical testing schedule may be delayed, resulting in the delay of our clinical programs and submission of product candidates for regulatory approval, which could cause our business to suffer. Our business could suffer if there are delays or difficulties in establishing relationships with manufacturers to produce, package, label and distribute our finished pharmaceutical or other medical products, if any, market introduction or subsequent sales of such products. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by the FDA. In this regard, the FDA will not issue a pre-market approval or product and establishment licenses, where applicable, to a manufacturing facility for the products until the manufacturing facility passes a pre-approval plant inspection. If we are unable to obtain or retain third party manufacturing on commercially acceptable terms, we may not be able to commercialize our products as planned. Our potential dependence upon third parties for the manufacture of our products may adversely affect our ability to generate profits or acceptable profit margins and our ability to develop and deliver such products on a timely and competitive basis.

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

We are subject to extensive governmental regulation which increases our cost of doing business and may affect our ability

to commercialize any new products that we may develop.

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The FDA and comparable agencies in foreign countries impose substantial requirements upon the introduction of pharmaceutical products through lengthy and detailed laboratory, preclinical and clinical testing procedures and other costly and time-consuming procedures to establish their safety and efficacy. All of our drugs and drug candidates require receipt and maintenance of governmental approvals for commercialization. Preclinical and clinical trials and manufacturing

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of our drug candidates are subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product. The status of our principal products is as follows:

- \* AP5346 has completed a Phase I clinical trial in Europe and has been approved for the commencement of a Phase I trial in the US by the FDA.
- \* Mucoadhesive liquid technology patient recruitment in the clinical trial is on hold pending commercial developments.
- \* Vitamin mediated delivery technology is currently in the pre-clinical phase.
- \* We also have other products in the preclinical phase.

Due to the time consuming and uncertain nature of the drug candidate development process and the governmental approval process described above, we cannot assure investors when we, independently or with our collaborative partners, might submit a New Drug Application, or "NDA", for FDA or other regulatory review.

Government regulation also affects the manufacturing and marketing of pharmaceutical products. Government regulations may delay marketing of our potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon our activities and furnish a competitive advantage to larger companies or companies more experienced in regulatory affairs. Delays in obtaining governmental regulatory approval could adversely affect our marketing as well as our ability to generate significant revenues from commercial sales. Our drug candidates may not receive FDA or other regulatory approvals on a timely basis or at all. Moreover, if regulatory approval of a drug candidate is granted, such approval may impose limitations on the indicated use for which such drug may be marketed. Even if we obtain initial regulatory approvals for our drug candidates, our drugs and our manufacturing facilities would be subject to continual review and periodic inspection, and later discovery of previously unknown problems with a drug, manufacturer or facility may result in restrictions on the marketing or manufacture of such drug, including withdrawal of the drug from the market. The FDA and other regulatory authorities stringently apply regulatory standards and failure to comply with regulatory standards can, among other things, result in fines, denial or withdrawal of regulatory approvals, product recalls or seizures, operating restrictions and criminal prosecution.

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

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Before we can obtain regulatory approvals for the commercial sale of any of our potential drugs, the drug candidates will be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. Preclinical

or clinical trials of any of our future drug candidates may not demonstrate the safety and efficacy of such drug candidates at all or to the extent necessary to obtain regulatory approvals. In this regard, for example, adverse side effects can occur during the clinical testing of a new drug on humans which may delay ultimate FDA approval or even lead us to terminate our efforts to develop the drug for commercial use. Like other companies in the biotechnology industry, we have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials. In particular, and polymer platinate has taken longer to progress through clinical trials than originally planned. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate. A delay or failure to receive

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regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in our attempts to further develop such candidates and obtain future regulatory approval.

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

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

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

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

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

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The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. Our competitors in the United States and elsewhere are

numerous and include, among others, major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions.

The following products may compete with polymer platinate:

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

The following companies are working on therapies and formulations that may be competitive

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with our polymer platinate:

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

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

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

Many of these competitors have and employ greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop technologies and drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

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

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

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The successful commercialization of, and the interest of potential collaborative partners to invest in the development of our drug candidates, may depend substantially upon reimbursement of the costs of the resulting drugs and related treatments at acceptable levels from government authorities, private health insurers and other organizations, including health maintenance organizations, or HMOs. The amount of such reimbursement in the United States or elsewhere may be decreased in the future or may be unavailable for any drugs that we may develop in the future. Limited reimbursement for



the cost of any drugs that we develop may reduce the demand for, or the price of such drugs, which would hamper our ability to obtain collaborative partners to commercialize our drugs, or to obtain a sufficient financial return on our own manufacture and commercialization of any future drugs.

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

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The drugs that we are attempting to develop may compete with a number of well-established drugs manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any drugs developed by us will depend on a number of factors, including the

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establishment and demonstration of the clinical efficacy and safety of our drug candidates, the potential advantage of our drug candidates over existing therapies and the reimbursement policies of government and third-party payers. Physicians, patients or the medical community in general may not accept or use any drugs that we may develop independently or with our collaborative partners and if they do not, our business could suffer.

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

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Lower prices for pharmaceutical products may result from:

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

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

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

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Our success depends, in part, on our ability to obtain U.S. and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate our business without infringing the proprietary rights of third parties. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under such patents are still developing and there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. The patent position of a biotechnology firm is highly uncertain and involves complex legal and factual questions. We cannot assure you that any existing or future patents issued to, or licensed by, us will not subsequently be challenged, infringed upon, invalidated or circumvented by others. As a result, although we, together with our subsidiaries, are either the owner or licensee to 11 U.S. patents and to 13 U.S. patent applications now pending, and 4 European patents and 13 European patent applications, we cannot assure investors that any additional patents will issue from

any of the patent applications owned by, or licensed to, us. Furthermore, any rights that we may have under issued patents may not provide us with significant protection against competitive products or otherwise be commercially viable.

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

- \* AP5280 in 2021
- \* AP5346 in 2021
- \* Mucoadhesive technology, patents are pending

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- \* Vitamin mediated technology between 2006 and 2019

In addition, patents may have been granted to third parties or may be granted covering products or processes that are necessary or useful to the development of our drug candidates. If our drug candidates or processes are found to infringe upon the patents or otherwise impermissibly utilize the intellectual property of others, our development, manufacture and sale of such drug candidates could be severely restricted or prohibited. In such event, we may be required to obtain licenses from third parties to utilize the patents or proprietary rights of others. We cannot assure investors that we will be able to obtain such licenses on acceptable terms, if at all. If we become involved in litigation regarding our intellectual property rights or the intellectual property rights of others, the potential cost of such litigation, regardless of the strength of our legal position, and the potential damages that we could be required to pay could be substantial.

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

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Due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified management, scientific and technical personnel. In view of the stage of our development and our research and development programs, we have restricted our hiring to research scientists and a small administrative staff and we have made only limited investments in manufacturing, production, sales or regulatory compliance resources. There is intense competition among major pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions for qualified personnel in the areas of our activities, however, and we may be unsuccessful in attracting and retaining these personnel.

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

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Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.) beneficially owned approximately 26.4% of our common stock as of September 30, 2005. Accordingly, he 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. He may exercise this ability in a manner that advances his best interests and not necessarily those of our other stockholders.

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

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Provisions of our Certificate of Incorporation, By-laws and

Stockholders Rights Plan may make it more difficult for a third party to acquire control of the company, even if a change in control would benefit our stockholders. In particular, shares of our preferred stock may be issued in the future without further stockholder approval and upon such terms and conditions, and having such rights, privileges and preferences, as our Board of Directors may determine, including, for example, rights to convert into our common stock. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any of our preferred stock that may be issued in the future. The issuance of our preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate

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purposes, could have the effect of making it more difficult for a third party to acquire control of us. This could limit the price that certain investors might be willing to pay in the future for shares of our common stock and discourage these investors from acquiring a majority of our common stock. Further, the existence of these corporate governance provisions could have the effect of entrenching management and making it more difficult to change our management.

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

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The market price for our common stock could drop as a result of sales of a large number of our presently outstanding shares or shares that we may issue or be obligated to issue in the future, including in connection with the SEDA. Substantially, all of the 17,630,040 shares of our common stock that are outstanding as of November 14, 2005, are unrestricted and freely tradable or tradable pursuant to a resale registration statement or under Rule 144 of the Securities Act.

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

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

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

For the year ended December 31, 2004, our management determined that our internal control systems over financial reporting was effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our auditors identified two material weaknesses in our internal controls and procedures during the course of their evaluation for the year ended December 31, 2004. If we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have an effective internal control system environment over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act. Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in our reported financial information, which could have a material

adverse effect on our stock price.

## ITEM 1 FINANCIAL STATEMENTS

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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

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This Quarterly Report on Form 10-Q contains certain statements that are forward-looking within the meaning of Section 27a of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, and that involve risks and uncertainties, including, but not limited to the uncertainties associated with research and development activities, clinical trials, our ability to raise capital, our ability to repay our outstanding debt obligations, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations, future cash flow, the timing and receipt of licensing and milestone revenues, the future success of our marketed products and products in development, our ability to achieve licensing milestones and other risks described below as well as those discussed elsewhere in this Form 10-Q, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission. Forward-looking statements contained in this Form 10-Q include, but are not limited to those relating to anticipated product approvals and timing thereof, the terms of future licensing arrangements, our ability to secure additional financing for our operations, our ability to repay our outstanding debt obligations, our ability to fund our operations through January 31, 2006 with our current cash reserves and without accessing our SEDA, and our expected capital expenditures.

## OVERVIEW

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We are an emerging pharmaceutical company developing unique polymer linked cytotoxics for the use in the treatment of cancer. The lead product AP5346 is in Phase II clinical testing. The Company also has other advanced drug delivery technologies including vitamin-mediated targeted delivery and oral care drug delivery.

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

- \* synthetic polymer targeted delivery,
- \* vitamin mediated targeted delivery,
- \* vitamin mediated oral delivery, and
- \* mucoadhesive liquid technology.

Since our inception, we have devoted our resources primarily to fund our research and development programs. We have been unprofitable since inception and to date have received limited revenues from the sale of products. We cannot assure investors that we will be able to generate sufficient product revenues to attain profitability on a sustained basis or at all. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance. As of September 30, 2005, our accumulated deficit was \$72,756,000.

We sold our oral care business to Uluru, Inc., a private Delaware company, for up to \$20.6 million. This transaction closed on October 12, 2005. This includes our interest in

Aphthasol(R), all OraDisc(TM) products, all Residerm(R) products, and all of our assets related to these products. In addition, we have licensed to Uluru our nanoparticle hydrogel aggregate technology which could be used for applications such as local drug delivery and tissue filler in dental and soft tissue applications. The CEO of Uluru is Kerry P. Gray, the former CEO of Access Pharmaceuticals, Inc. In conjunction with the sale transaction, we received a fairness opinion from a nationally recognized investment banking firm.

At the closing of this agreement we received \$8.7 million. In addition, at the one year anniversary

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of the agreement we may receive up to \$3.7 million, and we will receive an additional \$1 million within 24 months after closing or earlier upon the achievement of a milestone. Additional payments of up to \$7.2 million may be made upon the achievement of certain additional milestones.

We closed our laboratory in Australia. The development work completed in Australia will be completed in the Dallas laboratory while the animal work completed in Australia will be completed in contract facilities.

The upfront payment of this transaction allowed Access to immediately retire our \$2.6 million of Secured Convertible Notes held by Cornell Capital and its affiliate and the various agreements relating to these notes. Such notes were secured by all of our assets. In addition, the elimination of the manufacturing and regulatory costs associated with the oral care business, as well as required employees for these marketed products and product candidates will allow us to reduce our burn rate substantially.

#### 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 September 30, 2005 our cash and cash equivalents and short-term investments were \$470,000 and our working capital was \$(9,474,000). Our working capital at September 30, 2005 represented a decrease of \$1,686,000 as compared to our working capital as of December 31, 2004 of \$(7,788,000). The decrease in working capital was due mainly to the loss from operations for the nine months ended September 30, 2005 offset by additional capital and Secured Convertible Notes incurred by the Company and the reclassification from short term to long term of a portion of the convertible notes.

As of September 30, 2005, the Company had a working capital deficit of approximately \$9,474,000. As of that date, the Company did not have enough capital to achieve its near, medium or long-term goals. As of November 14, 2005 the Company had cash and cash equivalents of approximately \$1,024,000. Such liquid assets are expected to be able to fund operations through January 31, 2006 assuming no access to the SEDA or additional financings. We plan to access the SEDA and/or have additional financings.

We sold our oral care business to Uluru, Inc., a private Delaware company, for up to \$20.6 million. This transaction closed on October 12, 2005. At the closing of this agreement, we received \$8.7 million. In addition, at the one year anniversary of the agreement we may receive up to \$3.7 million, and we will receive an additional \$1 million within 24 months after closing or earlier upon the achievement of a milestone. Additional payments of up to \$7.2 million will be made upon the achievement of certain additional milestones.

As of March 30, 2005 the Company executed a Standby Equity Distribution Agreement (SEDA) with Cornell Capital Partners. Under the SEDA, the Company may issue and sell to Cornell Capital Partners common stock for a total purchase price of up to \$15,000,000. The purchase price for the shares is equal to their market price, which is defined in the SEDA as 98% of the lowest volume weighted average price of the common stock during a specified period of trading days following the date notice is given by the Company that it desires to access the SEDA. Further, we have agreed to pay Cornell Capital Partners, L.P. 3.5% of the proceeds that we

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receive under the Equity Line of Credit. The amount of each draw down is subject to a maximum amount of \$1,000,000. The terms of the SEDA do not allow us to make draw downs if the draw down would cause Cornell Capital to own in excess of 9.9% of our outstanding shares of common stock. Upon closing of the transaction, Cornell Capital Partners received a one-time commitment fee of 146,500 shares of the Company's common stock. On the same date, the Company entered into a Placement Agent Agreement with Newbridge Securities Corporation, a registered broker-dealer. Pursuant to the Placement Agent Agreement, upon closing of the transaction the Company paid a one-time placement agent fee of 3,500 shares of common stock. As of September 30, 2005 we have accessed \$600,000 of the SEDA. At this time the Company will not be able to access the SEDA until a post-effective amendment to our registration statement is filed with, and declared effective by, the SEC.

In addition, as of March 30, 2005, the Company executed a Securities Purchase Agreement with Cornell Capital Partners and Highgate House Funds. Under the Securities Purchase Agreement, upon closing Cornell Capital Partners and Highgate House Funds purchased an aggregate of \$2,633,000 principal amount of Secured Convertible Debentures from the Company (net proceeds to the Company of \$2,360,000). The Secured Convertible Debentures accrue interest at a rate of 7% per year and were to mature 12 months from the issuance date with scheduled monthly repayment commencing on November 1, 2005 to the extent that the Secured Convertible Debenture has not been converted to common stock. The Secured Convertible Debenture was convertible into the Company's common stock at the holder's option any time up to maturity at a conversion price equal to \$4.00. The Secured Convertible Debentures were secured by all of the assets of the Company. The Company had the right to redeem the Secured Convertible Debentures upon 3 business days notice for 110% of the amount redeemed. Pursuant to the Securities Purchase Agreement, the Company had required to issue to the holders an aggregate of 50,000 shares of common stock of the Company. The Secured Convertible Notes were paid in full on October 12, 2005 in conjunction with the sale of our oral care assets.

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

We have also issued an aggregate of \$13,530,000 of convertible notes, which were due in two parts - \$8,030,000 is due on September 13, 2005 and \$5,500,000 was due on September 13, 2008. The notes which bear interest at a rate of 7.7% per annum with \$1,042,000 of interest due annually on each September 13th.

On Nov. 9, 2005 we announced the restructuring and repayment of the 7.0% convertible promissory notes due September 13, 2005.

One holder of \$4 million worth of convertible notes (Oracle

Partners LP and related funds) agreed to amend their notes to a new maturity date, April 28, 2007, with the conversion price being reduced from \$5.50 per share to \$1.00 per share. In addition, the Company may cause a mandatory conversion of the notes into common stock if the Company's stock trades at a price of at least 1.5 times the conversion price for a minimum number of trading days. There is also a provision to allow for a minimum price for conversion in the event of a change of control.

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The Company was unable to reach a conversion agreement with the second holder of \$4 million worth of notes (Philip D. Kaltenbacher), and has instead settled his claim by paying him this amount plus expenses and interest as outlined in the terms of the note.

In October, at the closing of the asset sale to Uluru, Inc., the Company retired its \$2.6 million senior secured convertible notes. In addition to the amended convertible notes held by Oracle Partners and its affiliates, the Company has \$5.5 million of 7% convertible notes due Sept 13, 2010.

Status of Convertible Notes

Noteholder	Amount due at 7/01/05	Amount due at 11/14/05	Status
<b>\$13.5 Million Convertible Notes</b>			
Oracle Partners & Affiliates	\$4,015,000	\$4,015,000	New maturity date of 4/28/07; \$1.00 conversion price; plus other terms
Philip D. Kaltenbacher	\$4,015,000	\$-0-	Paid note 11/9/05
Noteholder (name not disclosed)	\$5,500,000	\$5,500,000	New maturity date of 9/13/10
<b>\$2.6 Million Secured Convertible Notes</b>			
Cornell Capital Partners and Highgate House Funds	\$2,633,000	\$-0-	Paid note and interest due on 10/12/05

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 September 30, 2005 of \$72,756,000. We expect that our existing capital resources will be adequate to fund our current level of operations through January 31, 2006 assuming no access to the SEDA or additional financings. We plan to access the SEDA and/or have additional financings. We cannot assure investors that we will be able to access the SEDA or that we will ever be able to generate significant product revenue or achieve or sustain profitability.

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

- \* our ability to raise financing in order to continue our operations;
- \* 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  
\* the ability to convert, repay or restructure our outstanding convertible notes.

#### THIRD QUARTER 2005 COMPARED TO THIRD QUARTER 2004

Our licensing revenue in the third quarter of 2005 and 2004 was \$49,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2005 and 2004 was from several agreements, including agreements related to various amlexanox projects and Residerm(R). On October 12, 2005 these products and associated agreements were sold and no further licensing revenues are from such products, although milestone payments may be received.

There were \$163,000 in product sales of Aphthasol(R) in the third quarter of 2005, as compared to \$106,000 in sales in the third quarter of 2004 an increase of \$57,000. Aphthasol(R) was sold on October 12, 2005 and no additional product sales will be made by the Company.

Royalty income in the third quarter of 2005 was \$25,000, as compared to \$30,000 in the third quarter of 2004, a decrease of \$5,000. The patents, the licensing agreements and the associated royalty income were sold in October 2005 and no further royalties are expected, although milestone payments may be made in connection with the sale of assets.

Total research spending for the third quarter of 2005 was \$893,000, as compared to \$1,406,000 for the same period in 2004, a decrease of \$513,000. The decrease in expenses was primarily due to:

- \* lower salary and related expenses (\$188,000) principally due to the reduction in staff;
- \* lower expenses associated with our Australian laboratory (\$119,000) which was closed;
- \* lower production and testing costs for Aphthasol(R) and start-up production costs for OraDisc(TM) A (\$98,000); and
- \* lower production costs for AP5346 (\$83,000); and
- \* other net decreases (\$25,000).

Our cost of product sales was \$123,000 in the third quarter of 2005, as compared to \$40,000 in the third quarter of 2004, an increase of \$83,000. Aphthasol(R) was sold on October 12, 2005.

Total general and administrative expenses were \$693,000 for the third quarter of 2005, a decrease of \$106,000 as compared to the same period in 2004. The decrease in spending was due primarily to the following:

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- \* lower property and franchise taxes (\$42,000);
- \* lower patent expenses (\$39,000);
- \* lower shareholder expenses (\$23,000);
- \* lower salary and related expenses (\$22,000); and
- \* lower other net decreases (\$4,000).



The decreases are offset by higher legal fees (\$24,000).

Depreciation and amortization was \$164,000 for the third quarter of 2005 as compared to \$169,000 for the same period in 2004 reflecting a decrease of \$5,000.

Total operating expenses in the third quarter of 2005 were \$1,873,000 as compared to total operating expenses of \$2,414,000 for the same period in 2004, a decrease of \$541,000.

Loss from operations in the third quarter of 2005 was \$1,636,000 as compared to a loss of \$2,229,000 for the same period in 2004, a decreased loss of \$593,000.

Interest and miscellaneous income was \$4,000 for the third quarter of 2005 as compared to \$133,000 for the same period in 2004, a decrease of \$129,000. The decrease in miscellaneous income of \$97,000 was due to foreign exchange gains on a Euro denominated receivable. This decrease was in addition to a decrease in interest income due to lower cash balances in 2005 as compared with 2004.

Interest and other expense was \$431,000 for the third quarter of 2005 as compared to \$332,000 for the same period in 2004, an increase of \$99,000 due principally to the addition in interest and amortization associated with the Secured Convertible Notes.

Net loss in the third quarter of 2005 was \$2,063,000, or a \$0.13 basic and diluted loss per common share, compared with net loss of \$2,428,000, or a \$0.16 basic and diluted loss per common share for the same period in 2004, a decreased loss of \$365,000.

#### NINE MONTHS ENDED SEPTEMBER 30, 2005 COMPARED TO NINE MONTHS ENDED SEPTEMBER 30, 2004

Our licensing revenue in the first nine months of 2005 was \$84,000, as compared to licensing revenue of \$97,000 in the same period of 2004, a decrease of \$13,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. Licensing revenue recognized in both 2005 and 2004 was from several agreements including agreements related to various amlexanox projects and ResiDerm(R). On October 12, 2005 these products and associated agreements were sold and no further licensing revenues are expected from such products, although milestone payments may be received.

There were \$481,000 in product sales of Aphthasol(R) in the first nine months of 2005, as compared to \$106,000 in sales in the same period of 2004, an increase of \$375,000. There was a supply interruption for Aphthasol(R) and there was no Aphthasol sales in 2004 until late September, while there were sales for each of the nine months in 2005. Aphthasol(R) was sold on October 12, 2005 and no additional product sales will be made by the Company.

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Royalty income for the first nine months of 2005 was \$76,000, as compared to \$70,000 in the same period of 2004, an increase of \$6,000 due to the sales of Zindaclin(R) in additional countries. The patents, the licensing agreements and the associated royalty income were sold in October 2005 and no further royalties are expected, although milestone payments may be made in connection with the sale of assets.

Total research spending for the first nine months of 2005 was \$3,652,000, as compared to \$3,831,000 for the same period in 2004, a decrease of \$179,000. The decrease in expenses was the result of:

\* lower salary and related expenses (\$166,000) principally due

to the reduction in staff;

- \* lower expenses associated with our Australian laboratory (\$86,000) which was closed;
- \* lower production and testing costs for Aphthasol(R) and start-up production costs for OraDisc(TM) A (\$21,000); and
- \* other net decreases (\$11,000).

The decrease in expenses was partially offset by higher production costs for AP5346 (\$105,000) in preparation of the start-up of the Phase II clinical trials.

Our cost of product sales was \$403,000 for the first nine months of 2005, as compared to \$97,000 in the same period of 2004, an increase of \$306,000. Aphthasol(R) was sold on October 12, 2005.

Total general and administrative expenses were \$3,198,000 for the first nine months of 2005, an increase of \$873,000 as compared to the same period in 2004. The increase in general and administrative expenses was due primarily to the following:

- \* expenses due to the separation agreement with our former CEO (\$839,000);
- \* royalty license expenses (\$150,000);
- \* higher legal expenses (\$118,000); and
- \* other net increases (\$22,000).

The increases in general and administrative expenses is offset by:

- \* lower patent expenses (\$137,000);
- \* lower salaries and related expenses (\$83,000); and
- \* lower shareholder and investor communications expenses (\$36,000).

Depreciation and amortization was \$494,000 for the first nine months of 2005 as compared to \$489,000 for the same period in 2004 reflecting an increase of \$5,000.

Total operating expenses in the first nine months of 2005 were \$7,747,000 as compared to total operating expenses of \$6,742,000 for the same period in 2004, an increase of \$1,005,000.

Loss from operations in the first nine months of 2005 was \$7,106,000 as compared to a loss of \$6,469,000 for the same period in 2004, an increased loss of \$637,000.

Interest and miscellaneous income was \$26,000 for the first nine months of 2005 as compared to \$201,000 for the same period in 2004, a decrease of \$175,000. The decrease in miscellaneous

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income of \$97,000 was due to foreign exchange gains on a Euro denominated receivable. This decrease was in addition to a decrease in interest income due to lower cash balances in 2005 as compared with 2004.

Interest and other expense was \$1,191,000 for the first nine months of 2005 as compared to \$1,064,000 for the same period in 2004, an increase of \$127,000 due principally to the addition in interest and amortization associated with the Secured Convertible Notes.

Net loss in the first nine months of 2005 was \$8,271,000, or a \$0.53 basic and diluted loss per common share, compared with a loss of \$7,332,000, or a \$0.49 basic and diluted loss per common share for the same period in 2004, an increased loss of \$939,000.

ITEM 3 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We invest our excess cash and short-term investments in certificates of deposit, corporate securities with high quality ratings, and U.S. government securities. These investments are not held for trading or other speculative purposes. These financial investment securities all mature in 2005 and 2006 and their estimated fair value approximates cost. Changes in interest rates affect the investment income we earn on our investments and, therefore, impact our cash flows and results of operations. A hypothetical 50 basis point decrease in interest rates would result in a decrease in annual interest income and a corresponding increase in net loss of approximately \$3,000. This estimated effect assumes no changes in our short-term investments at September 30, 2005. We do not believe that we are exposed to any other market risks, as defined under applicable SEC regulations. We are not exposed to risks for changes in commodity prices, or any other market risks.

#### ITEM 4 CONTROLS AND PROCEDURES

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

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

As previously reported in our Annual Report on Form 10-K for the fiscal year ended

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December 31, 2004 (the "Form 10-K"), our management concluded that our internal control over financial reporting was effective as of December 31, 2004. However, as disclosed in the Form 10-K, our independent auditors concluded that we have two material weaknesses in the areas of segregation of duties and as a result of an aggregation of three separate significant deficiencies where the effectiveness of the controls are dependent on segregation of duties, as set forth in their attestation report in the Form 10-K. Their conclusion also points out that "these material weaknesses did not result in any adjustments to the annual or interim consolidated financial statements ..." and that "this report does not affect (their) report dated March 31, 2005" reflecting their opinion on the financial statements.

Based on the criteria set forth in their attestation report in the Form 10-K, our independent auditors determined that proper segregation of duties do not exist within our accounting and finance area. While management believes that sufficient controls are in place, and that there is adequate segregation of duties within the business, it recognizes that this is a perceived material weakness and is taking the steps it believes are necessary to mitigate this risk. In particular, management and the Audit Committee have considered the need for

ongoing monitoring of internal controls under the Sarbanes-Oxley Act of 2002, as well as strengthening the internal controls of the business by the engagement of an outside accounting/finance consulting firm to perform quarterly procedures designed to assist in the maintaining and monitoring of an effective control environment and to mitigate the risk related to a lack of segregation of duties between senior accounting/finance personnel. The consulting firm is expected to report and take instructions directly from the Audit Committee although management will be involved in assisting in determining the scope of the quarterly and annual procedures. Terms and conditions of this engagement are still under consideration.

## PART II -- OTHER INFORMATION

### ITEM 1 LEGAL PROCEEDINGS

On or about September 27, 2005, Philip Kaltenbacher ("Kaltenbacher") filed an action against Access in the United States District Court for the Southern District of New York, which was subsequently transferred to the United States District Court for the Northern District of Texas (the "Texas Action"). Kaltenbacher claimed that in 2000 he had invested \$4,015,000 in Access and that Access had, in exchange, executed and issued to Kaltenbacher a 7.0% Convertible Subordinated Note, due September 13, 2005 (the "Note"). Kaltenbacher alleged, in his complaint, that Access was obligated to pay him \$4,015,000 because the due date, September 13, 2005, had passed. The time for Access to submit a formal answer in the Texas Action had not yet come due, but in communications with Kaltenbacher, Access conceded the amount of the Note and the due date, but required Kaltenbacher to present the original of the Note for payment, as was required in the Note. Kaltenbacher was unable or unwilling to do so.

Access and Kaltenbacher have now resolved the dispute, and executed a formal Settlement Agreement and Release dated November 8, 2005 (the "Agreement"). As part of the Agreement, Kaltenbacher also executed a separate Affidavit and Indemnification concerning the missing original Note. In exchange, Access paid Kaltenbacher for his monetary claims, including payment of \$4,015,000 that was due on the Note. Access and Kaltenbacher are in the process of

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arranging for the dismissal with prejudice of the Texas Action.

### ITEM 2 SALES OF UNREGISTERED EQUITY SECURITIES AND USE OF PROCEEDS

On September 13, 2005, the Company issued 951,244 shares of its common stock as payment of interest to the holders of its 7% convertible promissory notes. Such issuances were made in reliance upon the exemption from registration requirements of the Securities Act of 1933, as amended, provided by Section 4(2) thereof.

During the third quarter the Company sold 955,245 shares under its SEDA pursuant to an effective registration on Form S-1.

### 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

Exhibits:

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

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

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

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

\* 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.

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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: November 14, 2005 By: /s/ Rosemary Mazanet

-----  
Rosemary Mazanet  
Acting Chief Executive Officer  
(Principal Executive Officer)

Date: November 14, 2005 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>

	September 30, 2005	
	(unaudited)	December 31, 2004
	-----	-----
ASSETS		
<S>	<C>	<C>
Current assets		
Cash and cash equivalents	\$ 378,000	\$ 1,775,000
Short term investments, at cost	92,000	486,000
Accounts and other receivables	765,000	791,000
Inventory	44,000	125,000
Prepaid expenses and other current assets	645,000	1,093,000
Total current assets	1,924,000	4,270,000
	-----	-----
Property and equipment, net	864,000	1,040,000
Debt issuance costs, net	648,000	130,000
Patents, net	2,062,000	2,315,000

Licenses, net	88,000	125,000
Goodwill, net	1,868,000	1,868,000
Restricted cash and other assets	357,000	1,342,000
Total assets	<u>\$ 7,811,000</u>	<u>\$11,090,000</u>

#### LIABILITIES AND STOCKHOLDERS' DEFICIT

Current liabilities		
Accounts payable and accrued expenses	\$ 2,113,000	\$ 2,131,000
Accrued interest payable	567,000	311,000
Deferred revenues	1,880,000	1,119,000
Current portion of notes payable and other future obligations	6,838,000	8,417,000
Total current liabilities	11,398,000	12,058,000
Note payable, net of current portion	37,000	193,000
Convertible note	9,515,000	5,500,000
Total liabilities	20,950,000	17,751,000

#### Commitments and contingencies

#### Stockholders' deficit

Preferred stock - \$.01 par value; authorized 2,000,000 shares; none issued or outstanding	-	-
Common stock - \$.01 par value; authorized 50,000,000 shares; issued, 17,630,040 at September 30, 2005 and 15,524,734 at December 31, 2004	176,000	155,000
Additional paid-in capital	60,649,000	59,010,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Unamortized value of restricted stock grants	(159,000)	(309,000)
Treasury stock, at cost - 819 shares	(4,000)	(4,000)
Accumulated other comprehensive loss	(20,000)	(3,000)
Accumulated deficit	(72,736,000)	(64,465,000)
Total stockholders' deficit	(13,139,000)	(6,661,000)
Total liabilities and stockholders' deficit	<u>\$ 7,811,000</u>	<u>\$ 11,090,000</u>

</TABLE>

The accompanying notes are an integral part of these statements.

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#### Access Pharmaceuticals, Inc. and Subsidiaries Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited)

<TABLE>

<CAPTION>

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2005	2004	2005	2004
<u>&lt;S&gt;</u>				
<u>&lt;C&gt;</u>				
Revenues				
Licensing revenues	\$ 49,000	\$ 49,000	\$ 84,000	\$ 97,000
Product sales	163,000	106,000	481,000	106,000
Royalty income	25,000	30,000	76,000	70,000
Total revenues	237,000	185,000	641,000	273,000
<u>&lt;S&gt;</u>				
<u>&lt;C&gt;</u>				
Expenses				
Research and development	893,000	1,406,000	3,652,000	3,831,000
Cost of product sales	123,000	40,000	403,000	97,000

General and administrative	693,000	799,000	3,198,000	2,325,000
Depreciation and amortization	164,000	169,000	494,000	489,000
Total expenses	1,873,000	2,414,000	7,747,000	6,742,000
Loss from operations	(1,636,000)	(2,229,000)	(7,106,000)	(6,469,000)
Other income (expense)				
Interest and miscellaneous income	4,000	133,000	26,000	201,000
Interest and other expense	(431,000)	(332,000)	(1,191,000)	(1,064,000)
	(427,000)	(199,000)	(1,165,000)	(863,000)
Net loss	\$(2,063,000)	\$(2,428,000)	\$(8,271,000)	\$(7,332,000)

Basic and diluted loss per common share	\$(0.13)	\$(0.16)	\$(0.53)	\$(0.49)
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Weighted average basic and diluted common shares outstanding	15,845,091	15,469,071	15,700,084	15,041,216
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Net loss	\$(2,063,000)	\$(2,428,000)	\$(8,271,000)	\$(7,332,000)
----------	---------------	---------------	---------------	---------------

Other comprehensive loss				
Foreign currency translation adjustment	(1,000)	(6,000)	(17,000)	(21,000)
Comprehensive loss	\$(2,064,000)	\$(2,434,000)	\$(8,288,000)	\$(7,353,000)

</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>

Nine Months ended September 30,

	2005	2004
<S>	<C>	<C>
Cash flows from operating activities:		
Net loss	\$ (8,271,000)	\$ (7,332,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Warrants issued in payment of consulting expenses	-	42,000
Amortization of restricted stock grants	150,000	91,000
Stock issued for interest	609,000	-
Depreciation and amortization	494,000	489,000
Amortization of debt costs	297,000	138,000
Change in operating assets and liabilities:		
Accounts receivable	26,000	330,000
Inventory	81,000	(45,000)
Prepaid expenses and other current assets	448,000	198,000
Restricted cash and other assets	650,000	(266,000)
Accounts payable and accrued expenses	(24,000)	(346,000)
Accrued interest payable	256,000	472,000
Deferred revenues	681,000	(11,000)
Net cash used in operating activities	(4,603,000)	(6,240,000)
Cash flows from investing activities:		
Capital expenditures	(28,000)	(260,000)

Redemptions of short term investments and certificates of deposit	394,000	1,325,000	
Net cash provided by investing activities	366,000	1,065,000	
Cash flows from financing activities:			
Payments of notes payable	(353,000)	(289,000)	
Proceeds from secured notes payable	2,633,000	-	
Proceeds from SEDA, net of costs of \$23,000	577,000	-	
Proceeds from stock issuances, net of costs of \$647,000	-	9,249,000	
Net cash provided by financing activities	2,857,000	8,960,000	
Net increase (decrease) in cash and cash equivalents	(1,380,000)	3,785,000	
Effect of exchange rate changes on cash	(17,000)	(21,000)	
Cash and cash equivalents at beginning of period	1,775,000	727,000	
Cash and cash equivalents at end of period	\$ 378,000	\$ 4,491,000	
Cash paid for interest	\$12,000	\$334,000	
Supplemental disclosure of non-cash transactions			
200,000 shares of common stock issued pursuant to the SEDA and Secured Convertible Notes	\$500,000	\$-	
Value of restricted stock grants	-	136,000	
Issued common stock for interest on convertible notes	609,000	-	

</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  
 Nine Months Ended September 30, 2005 and 2004  
 (unaudited)

(1) Interim Financial Statements

The consolidated balance sheet as of September 30, 2005 and the consolidated statements of operations for the three and nine months ended September 30, 2005 and 2004 and the consolidated statements of cash flows for the nine months ended September 30, 2005 were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these interim financial statements be read in conjunction with the financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2004. The results of operations for the period ended September 30, 2005 are not necessarily indicative of the operating results which may be expected for a full year. The consolidated balance sheet as of December 31, 2004 contains financial information taken from the audited financial statements as of that date.

In preparing consolidated financial statements in conformity with accounting principles generally accepted in the United States of America, management is required to make estimates and assumptions that affect the reported amounts of assets and



liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

(2) Intangible Assets

Intangible assets consist of the following (in thousands):

<TABLE>

<CAPTION>

	September 30, 2005		December 31, 2004	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
Amortizable intangible assets				
Patents	\$3,179	\$1,117	\$3,179	\$864
Licenses	500	412	500	375
Total	\$3,678	\$1,528	\$3,678	\$1,238

</TABLE>

Amortization expense related to intangible assets totaled \$96,000 and \$105,000 for each of the three months ended September 30, 2005 and 2004, respectively and totaled \$290,000 and \$315,000 for the nine months ended September 30, 2005 and 2004, respectively. The aggregate estimated amortization expense for intangible assets remaining as of September 30 is as follows (in thousands):

	42
2005	\$ 97
2006	388
2007	363
2008	338
2009	338
Thereafter	626
Total	\$2,150

(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 September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Net loss as reported	\$(2,063,000)	\$(2,428,000)	\$(8,271,000)	\$(7,332,000)
Deduct: Stock-based employee compensation expense determined under fair value based method	(164,000)	(185,000)	(809,000)	(583,000)
Pro forma	\$(2,227,000)	\$(2,613,000)	\$(9,080,000)	\$(7,915,000)

Basic and diluted loss per share:				
As reported	\$ (0.13)	\$ (0.16)	\$ (0.53)	\$ (0.49)
Pro forma	(0.14)	(0.17)	(0.58)	(0.60)

</TABLE>

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

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Fully diluted shares	22,091,915	21,424,687	21,946,908	20,996,832

(4) Sale of Assets

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We sold our oral care business to Uluru, Inc., a private Delaware company, for up to \$20.6 million. This transaction closed on October 12, 2005. This includes our interest in Aphthasol(R), all OraDisc(TM) products, all Residerm(R) products, and all of our assets related to these products. In addition, we have licensed to Uluru our nanoparticle hydrogel aggregate technology which could be used for application such as drug delivery and tissue filler in dental and soft tissue applications. Beginning with the fourth quarter of 2005, the oral care operations will be presented as discontinued operation. The approximate total estimated net assets sold to Uluru is \$1,296,000.

(5) Shareholder's Equity

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On September 13, 2005, the Company issued 951,244 shares of its common stock as payment of interest to the holders of its 7% convertible promissory notes. Such issuances were made in reliance upon the exemption from registration requirements of the Securities Act of 1933, as amended, provided by Section 4(2) thereof.

During the third quarter the Company sold 955,245 shares under its SEDA pursuant to an effective registration on Form S-1.

CERTIFICATION

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

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

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

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

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

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

b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

registrant's internal control over financial reporting.

Date: November 14, 2005

/s/ Rosemary Mazaanet

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Rosemary Mazanet

Acting Chief Executive Officer

CERTIFICATION

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

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

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

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

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

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

b. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

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

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

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

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

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

registrant's internal control over financial reporting.

Date: November 14, 2005

/s/ Stephen B. Thompson

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Stephen B. Thompson  
Chief Financial Officer

EXHIBIT 32.1

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

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

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

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

Signed at the City of Dallas, in the State of Texas, this 14th day of November, 2005.

/s/ Rosemary Mazanet

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Rosemary Mazanet  
Acting Chief Executive Officer

EXHIBIT 32.2

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

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

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

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

Signed at the City of Dallas, in the State of Texas, this 14th day of November, 2005.

/s/ Stephen B. Thompson

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Stephen B. Thompson  
Chief Financial Officer