

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2008

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-9314

ACCESS PHARMACEUTICALS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware  
(State or Other Jurisdiction of  
Incorporation or Organization)

83-0221517  
(I.R.S. Employer  
Identification No.)

2600 Stemmons Freeway, Suite 176, Dallas, TX  
(Address of registrant's principal executive offices)

75207  
(Zip Code)

Registrant's telephone number, including area code: (214) 905-5100

Securities registered pursuant to Section 12(b) of the Act: None

**Title of Each Class**

Common Stock, \$0.01 par value

**Name of Each Exchange on Which Registered**

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 requirements for the past 90 days.  
Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the Registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer   
(Do not check if a smaller  
reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the average bid and asked price of such common equity, as of June 30, 2008, was approximately \$12,272,000.

The number of shares outstanding of the registrant's common stock as of March 30, 2009 was 11,315,272 shares. Also outstanding at March 30, 2009 there were 3,242.8617 shares of Series A Convertible Preferred Stock convertible into 10,809,539 shares of Common Stock.

**DOCUMENTS INCORPORATED BY REFERENCE.**

Portions of the registrant's definitive Proxy Statement relating to its 2009 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated.

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## PART I

### ITEM 1. BUSINESS

This Form 10-K (including the information incorporated by reference) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, that involve risks and uncertainties including, but not limited to the uncertainties associated with research and development activities, clinical trials, our ability to raise capital, the timing of and our ability to achieve regulatory approvals, dependence on others to market our licensed products, collaborations, future cash flow, the timing and receipt of licensing and milestone revenues, the future success of our marketed products and products in development, our sales projections, and the sales projections of our licensing partners, our ability to achieve licensing milestones and other risks described below as well as those discussed elsewhere in this 10-K, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission. These statements include, without limitation, statements relating to our ability to continue as a going concern, anticipated payments to be received from Uluru, anticipated product approvals and timing thereof, product opportunities, clinical trials and U.S. Food and Drug Administration (“FDA”) applications, as well as our drug development strategy, our clinical development organization, expectations regarding our rate of technological developments and competition, our plan not to establish an internal marketing organization, our expectations regarding minimizing development risk and developing and introducing technology, the size of our targeted markets, the terms of future licensing arrangements, our ability to secure additional financing for our operations and our expected cash burn rate. These statements relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “could,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of such terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Risk Factors,” that may cause our or our industry’s actual results, levels of activity, performance or achievements to be materially different from any future results, levels or activity, performance or achievements expressed or implied by such forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We are under no duty to update any of the forward-looking statements after the date of filing this Form 10-K to conform such statements to actual results.

#### Business

Access Pharmaceuticals, Inc. (together with our subsidiaries, “We”, “Access” or the “Company”) is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one approved product, one product at Phase 3 of clinical development, four products in Phase 2 of clinical development and four products in pre-clinical development. Low priority clinical and pre-clinical programs will be dependent on our ability to enter into collaborative arrangements. Our description of our business, including our list of products and patents, takes into consideration our acquisition of MacroChem Corporation which closed February 25, 2009.

- MuGard™ is our approved product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the Food & Drug Administration (“FDA”) and we expect approval and sales by our licensee in various EU countries in the first half of 2009.
- Our lead development candidate for the treatment of cancer is ProLindac™, a nanopolymer DACH-platinum prodrug. ProLindac just completed a Phase 2 clinical trial in the EU in patients with ovarian cancer patients. The clinical study had positive safety and efficacy results. We are currently planning a number of combination trials, looking at combining ProLindac with other cancer agents such as taxol and gemcitabine, in solid tumor indications including colorectal and ovarian. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has sales in excess of \$2.0 billion.
- Thiarabine, or 4-thio Ara-C, is a next generation nucleoside analog licensed from Southern Research Institute. Previously named SR9025 and OSI-7836, the compound has been in two Phase 1/2 solid tumor human clinical trials and was shown to have anti-tumor activity. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and intend to initiate additional Phase 2 clinical trials in adult AML, ALL and other indications.

- Pexiganan is a novel topical broad-spectrum antibiotic being developed for the treatment of mild-to-moderate diabetic foot ulcer infections. Pexiganan has been through two Phase 3 clinical trials, and data from these trials were presented last December 15, 2008 in the journal Clinical Infectious Diseases. We are actively seeking co-development partners for Pexiganan.
- EcoNail is a proprietary lacquer formulation of the anti-fungal econazole and our Soft Enhancement of Percutaneous Absorption (SEPA) technology for the treatment of onychomycosis. EcoNail recently completed a Phase 2 clinical trial and we are currently evaluating its development and partnering strategy.
- Phenylbutyrate (PB), an HDAC inhibitor and a differentiating agent, has been investigated in multiple Phase 1/2 NIH and clinician-sponsored trials, and is currently approved by the FDA for the treatment of hyperuremia, a pediatric orphan indication. For its use in cancer, phenylbutyrate is a Phase 2 clinical candidate.
- Cobalamin™ is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We are currently developing a product for the oral delivery of insulin, and are conducting sponsored development of a product for oral delivery of human growth hormone.
- Angiolix® is our preclinical humanized monoclonal antibody which acts as an anti-angiogenesis factor and is targeted to lactadherin, a glycoprotein secreted by cancer cells, notably breast, ovarian and colorectal cancers.
- Prodrax® is our non-toxic prodrug which is activated in the hypoxic zones of solid tumors to kill cancer cells. This product is in preclinical development.
- Cobalamin-mediated cancer targeted delivery is a preclinical technology which makes use of the fact that cell surface receptors for vitamins such as B12 are often overexpressed by cancer cells.

## Products

Access used its drug delivery technologies to develop the following products and product candidates:

### Access Drug Portfolio

<b>Compound</b>	<b>Originator</b>	<b>Technology</b>	<b>Indication</b>	<b>Clinical Stage (1)</b>
MuGard™	Access	Mucoadhesive liquid	Mucositis	(510k) Marketing clearance received
ProLindac™ (Polymer Platinate, AP5346) (2)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Thiarabine (4-thio Ara-C)	Southern Research Institute	Small molecule	Cancer	Phase 1/2
Pexiganan	Genaera Corp.	Small peptide	Diabetic foot ulcer infections	Phase 3
EcoNail	Access	SEPA	Onychomycosis	Phase 2
Phenylbutyrate (PB)	National Institute of Health	Small molecule	Cancer	Phase 2
Oral Insulin	Access	Cobalamin	Diabetes	Pre-clinical
Oral Delivery System	Access	Cobalamin	Various	Pre-clinical
Angiolix®	Immunodex, Inc.	Humanized monoclonal antibody	Cancer	Pre-clinical
Prodrax®	Univ of London	Small molecule	Cancer	Pre-clinical
<u>Cobalamin-Targeted Therapeutics</u>	Access	Cobalamin	Anti-tumor	Pre-clinical

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

(2) Licensed from the School of Pharmacy, The University of London. Subject to a 1% royalty and milestone payments on sales.

## **Approved Products**

### MuGard™ - Mucoadhesive Liquid Technology (MLT)

Mucositis is a debilitating condition involving extensive inflammation of mouth tissue that affects annually an estimated 400,000 cancer patients in the United States undergoing chemotherapy and radiation treatment. Any treatment that would accelerate healing and/or diminish the rate of appearance of mucositis would have a significant beneficial impact on the quality of life of these patients and may allow for more aggressive chemotherapy. We believe the potential addressable market for a mucositis product could be over \$1 billion world-wide.

Access' MuGard is a viscous polymer solution which provides a coating for the oral cavity. MuGard is dispensed in a ready to use form. A multi-site, randomized clinical study was performed in the United States testing MuGard and MuGard containing an anti-inflammatory drug to determine the effect of these products on the prevention and treatment of mucositis. The data from this trial indicated that the patients using MuGard displayed a lower incidence of mucositis than is typically seen in the studied population with no additional benefit from the drug.

The data were retrospectively compared with two historical patient databases to evaluate the potential advantages MuGard may provide in the prevention, treatment and management of mucositis. The patient evaluation was conducted using the oral mucositis assessment scale (OMAS), 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.

These data confirmed the fact that MuGard could represent an important advancement in the management and prevention of mucositis. On September 20, 2006, we announced that we had submitted a Premarket Notification 510(k) application to the United States Food and Drug Administration (FDA) announcing the Company's intent to market MuGard. On December 13, 2006, we announced that we had received marketing clearance for MuGard from FDA for the indication of the management of oral wounds including mucositis, aphthous ulcers and traumatic ulcers.

In August 2007, we signed a definitive licensing agreement with SpePharm Holding, B.V. under which SpePharm will market MuGard in Europe. MuGard sales are expected to start in the first six months of 2009 in Europe. In January 2008, we signed a definitive licensing agreement with RHEI Pharmaceuticals, Inc. under which RHEI will market MuGard in China and other Southeast Asian countries. In August 2008, we signed a definitive licensing agreement with Milestone Biosciences, LLC under which Milestone will market MuGard in the United States and Canada. Access is currently seeking marketing partners to market MuGard in other territories worldwide.

## **Products in Development**

### ProLindac™ (Polymer Platinite, AP5346) DACH Platinum

Chemotherapy, surgery and radiation are the major components in the clinical management of cancer patients. Chemotherapy serves as the primary therapy for some solid tumors and metastases and is increasingly used as an adjunct to radiation and surgery to improve their effectiveness. 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 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.

Oxaliplatin, a compound of DACH platinum, is a chemotherapeutic which was initially approved in Europe in 1999 for the treatment of colorectal cancer. It is now also being marketed worldwide and generated sales in excess of \$2 billion in 2006. Carboplatin and Cisplatin, two other approved platinum chemotherapy drugs, are not indicated for the treatment of metastatic colorectal cancer. Oxaliplatin, in combination with 5-fluorouracil and folinic acid (known as the FOLFOX regime) 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 940,000 reported new cases annually worldwide, increasing at a rate of approximately three percent per year, and 500,000 deaths.

Currently, platinum compounds are one of the largest selling categories of chemotherapeutic agents, with annual sales in excess of \$3.0 billion in 2006. As is the case with all chemotherapeutic drugs, the use of such compounds is associated with serious systemic side effects. The drug development goal therefore is to enhance delivery of the active drug to the tumor and minimize the amount of active drug affecting normal organs in the body.

Utilizing a biocompatible water-soluble polymer (HPMA) as a drug carrier, Access' drug candidate ProLindac, links DACH platinum to a polymer in a manner which permits the selective release of active drug to the tumor by several mechanisms. The main release mechanism takes advantage of the differential pH in tumor tissue compared to healthy tissue. The polymer also 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 of ProLindac to inhibit tumor growth has been evaluated in more than ten preclinical models. Compared with the marketed product oxaliplatin, ProLindac was superior, and in several cases markedly superior in most 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, ProLindac 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 ProLindac delivers approximately 14 times more platinum to tumor DNA than oxaliplatin. Results from preclinical efficacy studies conducted in the B16 and other tumor models have also shown that ProLindac is superior to oxaliplatin in inhibiting the growth of tumors. An extensive preclinical package has been developed supporting the development of ProLindac.

In 2005, we completed a Phase 1 multi-center clinical study conducted in Europe, which enrolled 26 patients. The study was reported in a journal publication, *Cancer Chemotherapy and Pharmacology*, 60(4): 523-533 in 2007. The European trial was designed to identify the maximum tolerated dose, dose limiting toxicities, the pharmacokinetics of the platinum in plasma and the possible anti-tumor activity of ProLindac. The open-label, non-randomized, dose-escalation Phase 1 study was performed at two European centers. ProLindac 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 obtained 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 number of cycles. Of the 16 evaluable patients, 2 demonstrated a partial response, 1 experienced a partial response based on a biomarker 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. The patient who experienced a partial response based on a biomarker was an ovarian cancer patient for whom Ca125 levels returned to normal. 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.

Enrollment in a Phase 2 clinical trial of ProLindac was completed late in 2008 in ovarian cancer patients who have relapsed after first line platinum therapy and second line therapies. The primary aim of the study was to determine the response rate of ProLindac monotherapy in this patient population. The response rates for other platinum compounds in this indication are reported, and were used for comparison. Patients were dosed either once every 2 weeks or once every three weeks. As the Phase 1 study involved weekly dosing, the initial phase of the ovarian cancer monotherapy study involved some dose escalation to determine recommended doses using these dosing regimens.

This 26 patient Phase 2 study explored 3 different dose levels and 2 dosing regimens of ProLindac as a monotherapy treatment for advanced ovarian cancer, to provide data on the monotherapy anticancer activity and safety of ProLindac. Of patients eligible for evaluation according to standard RECIST criteria, clinically-meaningful disease stabilization was achieved in 42% of all patients, and 66% of all patients in the higher dose groups. Sustained and significant reductions in Ca125, the established specific serum marker for ovarian cancer, were also observed in several patients.

We reported positive safety and efficacy results from this Phase 2 monotherapy clinical study of ProLindac™ in late-stage, heavily pretreated ovarian cancer patients. No patient in any dose group exhibited any signs of acute neurotoxicity, which is a major adverse side-effect of the approved DACH platinum, Eloxatin, and ProLindac was well tolerated overall. The maximum tolerated dose of ProLindac was established as well as the recommended dose levels for future combination studies.

ProLindac was well tolerated in an absolute sense and relative to commercially-available platinum therapies. We saw significant DACH platinum activity and efficacy in patients at the highest dose levels which is very encouraging given that this study involved monotherapy in a heavily pretreated patient population that typically only respond to aggressive drug combinations. The DACH platinum activity level seen benchmarked favorably with published studies of monotherapy oxaliplatin in similar but less heavily pre-treated patient populations. Having achieved the recommended dose for future combination studies, we look forward to moving ahead in the clinic ourselves and with our regional partners.”

We previously submitted an IND application to the US Food and Drug Administration, and received clearance from the agency to proceed with a Phase 1 clinical study of ProLindac in combination with fluorouracil and leucovorin. The study is designed to evaluate the safety of ProLindac in combination with two standard drugs used to treat colorectal cancer and to establish a safe dose for Phase 2 clinical studies of this combination in colorectal cancer. We are currently evaluating various options for combination trials, to be conducted either within the US or in other countries. We are looking at combining ProLindac with other cancer agents, such as taxol and gemcitabine, in multiple solid tumor indications including colorectal and ovarian.

#### Thiarabine (4-thio Ara-C)

Our product candidate Thiarabine (SR-9025 or 4'-thio-beta-D-arabinofuranosylcytosine) is a new generation nucleoside analogue which was invented by Southern Research Institute of Birmingham, Alabama. This compound is within a certain class of anti-cancer drugs generally characterized as cytotoxic agents with proven success in certain blood-borne cancers.

Thiarabine exhibited significant activity, including regressions or cures, in six tested leukemia or lymphoma cell lines. The compound produced better activity than ara-C or a fatty acid-modified ara-C (depot) analog in four of six tested models. Thiarabine also performed as well or better than clofarabine and gemcitabine in each of the models.

Unlike ara-C, thiarabine was found to be active in a wide variety of solid tumor xenograft models (14 different cell lines), including colorectal, lung, renal, prostate, breast and pancreatic tumors, mainly via intraperitoneal administration (one model was done iv). Thiarabine produced regressions or tumor-free survivors in about half of the models and exhibited better activity than gemcitabine or clofarabine in many models. Thiarabine activity was also better than that of paclitaxel or cisplatin in certain lung models. An increase in regression or cure rate over either compound alone was observed with combinations of thiarabine and cisplatin in lung tumors, thiarabine and irinotecan or clofarabine in colorectal tumors, and thiarabine plus clofarabine in a leukemia model.

Two phase 1 studies were conducted of thiarabine monotherapy in patients with solid tumors.

In the first phase 1 study, 26 patients with incurable advanced and/or metastatic solid tumors were enrolled. The protocol involved doseescalation, starting at 100 mg/m<sup>2</sup> iv over 30 minutes on days 1 and 8, every three weeks. Patients were dosed at 200, 400, 500, and 600 mg/m<sup>2</sup>.

Out of 21 evaluable patients, 9 experienced stable disease (median duration 4.3 months, range 1.8-6.4 months).

Dose-limiting toxicities (DLTs) were observed at 400-600 mg/m<sup>2</sup>. Unlike previous observations with gemcitabine and ara-C (where the DLT is myelosuppression; leucopenia and thrombocytopenia), there were no grade four toxicities and no hematological toxicities other than reversible, lymphopenia. Investigators concluded that the (Grade 3) dose-limiting toxicities were fatigue, rash, fever, seizure and lymphopenia.

A second solid tumor phase 1 trial was carried out to explore other schedules. The schedules were 200 mg/m<sup>2</sup> via 60-minute IV infusion every 21 days, 5-minute bolus on same schedule, and 5-minute bolus weekly for 4 weeks starting with a dose of 100 mg/m<sup>2</sup>. Of the 27 evaluable patients, 7 patients (bladder cancer and mesothelioma) achieved disease stabilization (median 3.7 months, range 1.9-5.4). The main toxicity was fatigue, which appeared to be schedule independent.

The excellent results seen for thiarabine in leukemia and lymphoma preclinical models and the lymphopenia observed in clinical studies provides a strong rationale for further investigation of thiarabine in leukemia and lymphoma patients. Access plans to initiate further thiarabine clinical studies in at least one of these patient populations subject to funding or partnering.

### Sodium Phenylbutyrate

Sodium Phenylbutyrate, or PB, is a small molecule that was previously approved by the FDA for sale as a treatment for a rare genetic disorder in infants known as hyperuremia. PB has a number of additional mechanisms of action, including the inhibition of histone deacetylase. Histone deacetylase is a class of enzymes that remove acetyl groups from the amino acids in DNA. The inhibition of histone deacetylase allows the body's cancer suppressing genes to work as intended. In addition, PB is not toxic to cells. These characteristics make PB a good candidate to become a chemopotentiator; that is, a substance that enhances the activity of a chemotherapeutic agent. As a result, PB will ideally be administered in conjunction with radiation and/or chemotherapy.

We are a party to a sublicense agreement with VectraMed, Inc. for the rights to develop and commercialize PB worldwide for the treatment of cancer, autoimmune diseases and other clinical indications. VectraMed obtained its rights to the product under an Exclusive Patent License Agreement dated May 25, 1995 with the U.S. Public Health Service, representing the National Institutes of Health. VectraMed subsequently assigned all its rights to PB to us pursuant to a novation agreement dated May 10, 2005. These patents expire at various times between 2011 and 2016.

Phenylbutyrate has been the subject of numerous Phase 1 and Phase 2 clinical studies sponsored by the National Cancer Institute and others demonstrating the safety and efficacy of PB in cancer, both as a monotherapy and in combination with other anticancer compounds. To date, we have not been involved in any capacity in the conduct of any clinical trial related to PB.

We believe that PB may be a candidate to become a biological-response modifier that acts as a dose-dependent inhibitor of cancer cell proliferation, migration, and invasiveness, possibly by inhibition of urokinase and c-myc pathways, which means that it inhibits the protease activity that irreversibly induces programmed cell death. In addition, we believe that PB shows potential for the treatment of malignant gliomas, which are cancers of the brain. We are aware of numerous products in development for brain cancers. We are aware of several products being developed by academic and commercial organizations targeting glioblastoma. Medicis Pharmaceuticals currently sells Sodium Phenylbutyrate (Buphenyl<sup>®</sup>) for the treatment of a urea cycle disorder, hyperuremia.

There are thirteen key use patents related to PB which have been issued to the NIH and licensed by us.

PB has potential to be used in combination to treat many different types of cancer. One of the more promising unmet needs for which PB has previously shown potential is glioblastoma, and we are evaluating whether to support additional clinical trials for this indication. PB also has shown considerable promise to be used as a topical medication to treat radiation dermatitis. A cream formulation of PB has been developed. We are looking for a partner to complete this work with PB.

### **Drug Development Strategy**

With the acquisition of Somanta Ltd. in 2008 and MacroChem Corporation in 2009, Access has a rich pipeline of products ranging from preclinical development candidates to one approved product. To maximize return on this portfolio, we have elected to sell the rights to some of the products so that we can focus our efforts on the development of the remaining products. Products being harvested for cash include MuGard, Pexiganan, EcoNail and Phenylbutyrate. Products and technologies that we are continuing to develop in-house and with collaborators are ProLindac, Thiarabine, Cobalamin, Angiolix, and Prodrax.

A part of our integrated drug development strategy is to form alliances with centers of excellence in order to obtain alternative lead compounds while minimizing the overall cost of research. The Company does not spend significant resources on fundamental biological research but rather focuses on its chemistry expertise and clinical development. For example, certain of our polymer platinate technology has resulted in part from a research collaboration with The School of Pharmacy, University of London.

Our strategy is to focus on our polymer therapeutic program for the treatment of cancer while continuing to develop technologies such as Cobalamin-mediated oral drug delivery and Cobalamin-mediated tumor targeting which could provide us with a revenue stream in the short term through commercialization or outlicensing to fund our longer-term polymer and oncology drug development programs such as Angiolix, Prodrax and Thiarabine. 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 co-develop with or to outlicense to marketing partners our therapeutic product candidates. By forming strategic alliances with pharmaceutical and/or biotech companies, we believe that our technology can be more rapidly developed and successfully introduced into the marketplace.

We will continue to evaluate the most cost-effective methods to advance our programs. We will contract certain research and development, manufacturing and manufacturing scaleup, certain preclinical testing and product production to research organizations, contract manufacturers and strategic partners. As appropriate to achieve cost savings and accelerate our development programs, we will expand our internal core capabilities and infrastructure in the areas of chemistry, formulation, analytical methods development, clinical development, biology and project management to maximize product opportunities in a timely manner.

### **Process**

We begin the product development effort by screening and formulating potential product candidates, selecting an optimal active component, developing a formulation, 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 limited core internal development capability with significant experience in developing these formulations, but also depend upon the skills and expertise of our contractors.

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 1 and Phase 2 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 3 clinical studies we expect to engage a contract research organization to perform this work.

We contract with third party contract research organizations (CROs) to complete our large clinical trials and for data management of all of our clinical trials. Currently, we are preparing for two Phase 2 ProLindac trials to be completed by our licensees in China and Korea. Our licensees are funding these trials. We are also planning for additional Phase 2 clinical studies in France during 2009 subject to our ability to fund such trial. Our licensees for MuGard are planning for additional clinical studies to strengthen marketing claims

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 \$12,613,000 and \$2,602,000 on research and development during the years 2008 and 2007, respectively.

### **Scientific Background**

Access possesses a broad range of technologies and intellectual property in the areas of drug delivery and oncology. Our core technologies rely on the use of nanoparticles for use in the management of oral conditions such as mucositis, and in drug delivery. In addition, we have small molecule and monoclonal antibody programs which also embody the principals of drug delivery and drug targeting.

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

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

### **Core Drug Delivery Technology Platforms and Technologies**

Our current drug delivery technology platforms for use in cancer chemotherapy are:

- Synthetic Polymer Targeted Drug Delivery Technology;
- Cobalamin<sup>TM</sup>-Mediated Oral Delivery Technology;
- Cobalamin<sup>TM</sup>-Mediated Targeted Delivery Technology;
- Angiolix®; and
- Prodrax®.

Our other drug delivery technologies are:

- Pexiganan; and
- EcoNail.

Each of these platforms is discussed below:

### **Synthetic Polymer Targeted Drug Delivery Technology**

In collaboration with The School of Pharmacy, University of London, we have developed a synthetic polymer technology, which utilizes a hydroxypropylmethacrylamide (HPMA) polymer with platinum, designed to exploit enhanced permeability and retention, or EPR, at tumor sites to selectively accumulate drug and control drug release. This technology is employed in our lead clinical program, ProLindac. 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. Utilizing the principles of prodrugs, the drug is essentially inert while attached to the polymer, but is released inside the tumor mass while polymer/drug not delivered to tumors is cleared from the body via the kidneys. For example, ProLindac is attached to a pH-sensitive linker which releases the platinum cytotoxic agent much faster in the low pH environments found typically outside of hypoxic tumor cells and within specific compartments inside of tumor cells. 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.

## **Cobalamin™-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 coadministering the protein or peptide with permeation enhancers, which assist in passive transit through the gut wall or by 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.

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 Cobalamin (analogs of VB12) will still be transported by this process even when drugs, macromolecules, or nanoparticles are coupled to the Cobalamin. Thus Cobalamin 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 Cobalamin. If the capacity of the Cobalamin 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 which Cobalamin 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 Cobalamin. 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 nanoparticle volume compared with the size of the drug.

Our proprietary position in this technology involves the conjugation of Cobalamin and/or folic acid and/or biotin (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 vitamin-drug conjugates.

## **Cobalamin™-Mediated Targeted Delivery Technology**

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 Cobalamin-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 a vitamin analog, the analog 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 receptors on cancer cells, which makes them more sensitive to treatment regimes that target these cell surface receptors and differences in blood supply within and around tumor cells compared with normal cells.

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

- passive tumor targeting involves transporting anti-cancer agents through the bloodstream to tumor cells using a “carrier” molecule. Many different carrier molecules, which can take a variety of forms (micelles, nanoparticles, liposomes and polymers), are being investigated as each provides advantages such as specificity and protection of the anti-cancer drug from degradation due to their structure, size (molecular weights) and particular interactions with tumor cells. Our polymer platinate program is a passive tumor targeting technology.
- active tumor targeting involves attaching an additional fragment to the anticancer drug and the carrier molecule to create a new “targeted” agent that will actively seek a complementary surface receptor 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 Cobalamin compounds (analogs of vitamin B12), but we have also used and have certain intellectual property protection for the use of folate and biotin which may more effectively target anti-cancer drugs to certain 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 hematopoietic cells and methotrexate-sensitive tumors.

### **Angiolix®**

Angiolix (huMc-3) is a humanized monoclonal antibody targeting a glycoprotein known as lactadherin. Lactadherin promotes the growth of new blood vessels (angiogenesis) to support tumor growth. Angiolix, by blocking lactadherin, has the potential to induce programmed cell death, or apoptosis, in blood vessels supporting tumors. Angiolix was sublicensed from Immunodex, Inc., who licensed the product from the Cancer Research Institute of Contra Costa. Under that agreement, we are required to meet certain development targets, and make certain payments including an annual license maintenance fee and milestone payments.

We believe that Angiolix has a large market potential in the treatment of cancer. Avastin® is a marketed anti-angiogenesis monoclonal antibody that is effective by using a similar mechanism to that of Angiolix, and is used in the treatment of colorectal and other cancer types. Angiolix is unique in that it targets a propriety gene product which is expressed by cancerous tumors. We are not aware of any other organization developing similar products targeting this protein. The key patent relating to Angiolix has been issued in the U.S. and Australia. In general, it covers the composition of matter and various aspects of the binding to applicable antigens as well as the manufacture of Angiolix. We also have foreign counterparts to this patent pending in the European Union and Canada.

Angiolix is a humanized monoclonal antibody. Humanization is a process by which genetic material from a mouse cell is made tolerable to humans, using a patented technology developed by the National Institute of Health. The NIH previously granted to the Cancer Research Institute of Contra Costa a license to the applicable humanization technology. Pursuant to the Immunodex agreement, Immunodex and the Cancer Research Institute of Contra Costa are seeking to obtain for us the NIH's consent to a sublicense to us of the Cancer Research Institute of Contra Costa right to use the NIH humanization technology.

We have an agreement with an academic investigator for the development of Angiolix. We intend to complete preclinical development of Angiolix through the contributions of this investigator and through a contract manufacturer and contract testing laboratories. As a result we anticipate beginning a Phase 1 clinical study of Angiolix in 2010.

#### **Prodrax®**

Prodrax is a prodrug technology whereby non-toxic small molecule anticancer drugs become highly cytotoxic in low oxygen tumors by irreversible conversion to a form capable of binding to the DNA in tumor cells. This binding of DNA can result in tumor cell death. Prodrax molecules are di-N-oxides of chloroalkylaminoanthraquinone derivatives. We have a license to this technology from the University of London School of Pharmacy.

Prodrax is inert in normally oxygenated cells and becomes toxic in low oxygen areas, enabling it to kill tumor cells. Many solid tumors have a low oxygen area that is resistant to radiation and conventional chemotherapy. These cells repopulate the tumor with additional tumor cells that may be resistant to radiation and conventional chemotherapy. These cells are often referred to as quiescent. Cancer stems cells, now thought by many experts to be the progenitor of cancer spread (metastasis) throughout the body, are normally able to reside in hypoxic tumor regions unaffected by most anticancer therapies, which are only able to attack tumor cells which have a good blood and oxygen supply. Thus Prodrax has the potential to curtail tumor growth and progression by causing cell death in tumor regions normally unaffected by anticancer agents.

Prodrax becomes irreversibly converted to its toxic form in low oxygen tumor cells where it remains localized. When the surrounding oxygenated cells are killed by radiotherapy or chemotherapy, these Prodrax-containing quiescent cells move closer to the oxygen source and attempt to resume more active replication. It is in this state that they are killed by Prodrax, through potent DNA damage.

When given in conjunction with radiotherapy or conventional chemotherapy we expect Prodrax to result in significant improvement of tumor clearance and to reduce the likelihood of tumor repopulation, improving disease free survival. It is estimated that over 50% of all solid tumors exhibit clinically significant hypoxia, or low oxygenation, and that over two million people in the U.S. and Europe suffer from solid tumor cancers. If successful, Prodrax could improve the prognosis for a significant number of cancer sufferers in a wide range of tumor types.

In a 2-year research agreement with the University of Bradford in the UK, which expired in March 2008, several Prodrax molecules were made and tested, and two lead compounds were identified. Additional testing is required in order to select a primary lead which will be taken forward into clinical development. We expect to identify the lead in the first half of 2009.

### **Pexiganan for mild diabetic foot infections**

We acquired in the MacroChem acquisition the exclusive worldwide rights for drug uses of pexiganan, a novel, small peptide anti-infective for topical treatment of patients with mild diabetic foot infection (DFI). These rights were acquired from Genaera in October 2007.

There continues to be a very large and growing incidence of diabetes, approximately 20 million diabetics in the U.S. alone, and as a result a growing number of diabetic foot infections in the U.S. There is also a lack of effective topical anti-infectives to treat diabetic foot infection. We believe that pexiganan could fill an important unmet medical need for a topical anti-infective treatment and provide a significant commercial opportunity with an addressable market of approximately 3.5 million diabetic foot infections annually. Diabetic foot ulcers are normally treated by systemic antibiotics, giving rise to adverse side-effect and contributing to the increase of resistant bacteria.

Clinical trials previously conducted by Genaera include two Phase 3 trials submitted in a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in 1998. At that time, outstanding issues with CMC (Chemistry, Manufacturing and Controls) and an FDA request for one additional controlled trial precluded approval. MacroChem had made progress in addressing the CMC issues. In recent years there have been many advances in the manufacture of peptides, a better understanding of the treatment of diabetic foot infection, improvements in clinical trial design and execution, and more clarity concerning regulatory requirements for topical anti-infectives.

### **EcoNail for Onychomycosis**

Onychomycosis, a fungal infection of the nail, is predominantly an infection of the toe nail bed and nail plate underlying the surface of a nail. Typical symptoms of onychomycosis can include:

- nail discoloration;
- nail thickening;
- cracking and fissuring of the nail plate; and
- in severe cases, inflammation, pain and secondary infection of the nail bed and adjacent skin.

According to *Fitzpatrick's Dermatology in General Medicine (Sixth Edition)*, onychomycosis is a common disease, the prevalence of which varies by geographic region and ranges from approximately 2% to 18% of the worldwide population, with up to 48% of the population experiencing onychomycosis at least once by age 70. According to an article published in 2000 in the *Journal of the American Academy of Dermatology*, a large scale study found that the prevalence of onychomycosis in the normal population of North America was approximately 14%.

Current treatment options for onychomycosis include oral drugs, debridement (filing, trimming and scraping), nail avulsion (surgical or chemical excision of the infected nail plate) and drug therapies. There are two oral therapies marketed for the treatment of onychomycosis in the U.S.: Lamisil (terbinafine) and Sporanox (itraconazole). The leading oral treatment, Lamisil, has a complete cure rate of approximately 38%, but also has a 15% relapse rate. Sporanox has a complete cure rate of approximately 14%. Complete cure refers to mycological cure, or simultaneous occurrence of a negative KOH (a potassium hydroxide staining method for direct microscopic examination of nail scrapings) and a negative fungal culture, plus clinical cure, or clearance of all signs of infection. One risk associated with each of the oral treatments, both of which undergo substantial first pass metabolism by the liver, is liver disease. As a result, patients must continually monitor their liver function for signs of failure, including fatigue, anorexia, nausea and/or vomiting, jaundice, dark urine or pale stools. Such monitoring typically requires blood tests and associated office visits, which can impact patient compliance. In the rare case that liver failure occurs, it can result in death or the need for a liver transplant. Mechanical debridement, which is a traditional podiatric approach to onychomycosis that reduces the thickness of the nail, is not a cure for onychomycosis and requires time, specialized instruments and experience. Nail avulsion, which requires surgical or chemical removal of the nail plate causes discomfort and traumatizes the nail bed.

The only topical onychomycosis drug currently marketed in the U.S. is Penlac® (ciclopirox), a nail lacquer which has a complete cure rate of less than 10% and requires up to 48 weeks of treatment, including periodic removal of any unattached infected nail by a health care professional.

Typically delivered lacquer formulations, like EcoNail, have specific advantages over other existing oral treatments because they are applied like nail polish, treat fungal nail infections locally, and facilitate close and extended contact between an antifungal drug and the outer, or dorsal, nail surface. Developers of topical nail lacquers for onychomycosis face two major challenges. First, lacquers with acceptable hardness, durability and drying time tend not to release antifungal drugs from the lacquer matrix readily. Second, most antifungal drugs do not penetrate into the deep, or ventral, nail plate adequately when applied to the outer, or dorsal, nail surface, which results in insufficient antifungal concentrations at the site of infection.

EcoNail is a topically applied lacquer formulation based on MacroChem's proprietary SEPA (Soft Enhancer of Percutaneous Absorption) topical drug delivery technology, and containing econazole, for the topical treatment of onychomycosis. Econazole, a topical antifungal agent, effectively inhibits *in vitro* growth of the fungi most commonly implicated in onychomycosis. In contrast to SEPA's action in disrupting the lipid bilayer of the skin, SEPA as used in EcoNail works to soften the lacquer in which econazole is contained, thereby allowing for more rapid and complete release of econazole from the lacquer into and through the nail. A 14-day study of lacquers containing radioactively labeled econazole on human non-diseased cadaver nails demonstrated that EcoNail delivered approximately seven times more econazole to the ventral nail and 200 times more econazole to the nail bed than a similar lacquer without SEPA. In this study, EcoNail delivered to the ventral nail more than 14,000 times the minimum concentration of econazole needed to inhibit the two most common fungi associated with onychomycosis. In addition, we believe that EcoNail, as a locally applied lacquer, will have a reduced risk of systemic side effects compared with oral treatments for onychomycosis.

Following MacroChem laboratory studies, MacroChem conducted a Phase 1 tolerance/human exposure clinical trial of EcoNail in patients with onychomycosis and released six week safety and tolerance data from that trial in November 2004. The trial was a randomized, double-blind, controlled Phase 1 trial conducted at two U.S. clinical sites. Nineteen patients with onychomycosis of the toenails completed the safety-tolerability segment of the study, in which all fingernails and toenails were treated twice daily for six weeks with either EcoNail or a control nail lacquer. The six week safety-tolerability segment was followed by an open-label segment of the trial in which all patients received EcoNail applied once daily to all nails for an additional 12 weeks to extend patient exposure experience.

The main objectives of this Phase 1 study were to test the safety and local tolerability of EcoNail in patients with onychomycosis and to determine systemic exposure to econazole. In this study, EcoNail was well tolerated, and investigators reported no serious drug-related adverse events. Serum assays showed no detectable levels of econazole, further supporting EcoNail's systemic safety profile. Full data from the 18 week trial were presented in May 2005 at the annual meeting of the Society for Investigative Dermatology.

MacroChem commenced a 48 week, blinded open label Phase 2 efficacy study of EcoNail in the third quarter of 2006. This study was being conducted through a contract research organization with significant experience in onychomycosis trials. The study protocol allows for an interim review of the data after all patients have completed 24 weeks of treatment. On November 6, 2007, MacroChem announced that clinical photographs of 37 patients were assessed by an external expert panel, and 20 (54%) showed evidence of clinical improvement, defined as an increase in uninvolved nail of onychomycosis. All week 24 cultures were negative for dermatophyte growth, and the panel observed no signs of local irritation related to the once-daily EcoNail treatment. In a consensus clinical judgment by the external panel, 13 of 37 (32%) of patients demonstrated greater than or equal to 25% clinical improvement.

#### **Other Key Developments**

On March 5, 2009, we announced results from our Phase 2 ovarian cancer clinical trial. We reported positive safety and efficacy results from our Phase 2 monotherapy clinical study of ProLindac™ in late-stage, heavily pretreated ovarian cancer patients. In this monotherapy study 66% of patients who received the highest dose achieved clinically meaningful disease stabilization according to RECIST criteria. No patient in any dose group exhibited any signs of acute neurotoxicity, which is a major adverse side-effect of the approved DACH platinum, Eloxatin, and ProLindac was well tolerated overall. The maximum tolerated dose of ProLindac was established as well as the recommended dose levels for future combination studies.

On February 25, 2009, we closed our acquisition of MacroChem Corporation through the issuance of an aggregate of approximately 2.5 million shares of our common stock. In addition, we cancelled all of the outstanding debt of MacroChem in exchange for the issuance of 859,172 shares of our unregistered common stock.

On September 3, 2008, we announced that we had retained Piper Jaffray to augment ongoing business development efforts with the goal of establishing additional strategic development and commercialization partnerships for our product pipeline. The Piper Jaffray healthcare investment banking team will focus on partnering opportunities for ProLindac, Angiolix and the Cobalamin programs.

On August 27, 2008, we entered into a Note Purchase Agreement with MacroChem Corporation in order for Access to loan MacroChem amounts to keep certain of their licenses and vendors current. As of December 31, 2008, we had loaned MacroChem \$635,000.

On August 18, 2008, we announced the signing of a definitive licensing agreement under which Milestone Biosciences, LLC will market MuGard in the United States and Canada.

On June 4, 2008, we announced the signing of a definitive licensing agreement with Jiangsu Aosaikang Pharmaceutical Co., Ltd (“ASK”). Under this agreement ASK will manufacture, develop and commercialize our proprietary product ProLindac for the Greater China Region which includes the People’s Republic of China, the Hong Kong Special Administrative Region, the Macau Special Administrative Region and Taiwan. Under the terms of the agreement ASK paid Access an upfront fee and will pay subsequent milestone payments along with a royalty upon commercialization of ProLindac. In addition, in cooperation with Access, ASK has committed to fund two Phase 2 studies for ProLindac in colorectal cancer and one other indication to be determined by both parties.

On February 4, 2008, we entered into securities purchase agreements (the “Purchase Agreements”) with accredited investors whereby we agreed to sell 272.5 shares of our preferred stock, designated “Series A Cumulative Convertible Preferred Stock”, par value \$0.01 per share, for an issue price of \$10,000 per share, (the “Series A Preferred Stock”) and agreed to issue warrants to purchase 499,584 shares of our common stock, which includes placement agent warrants to purchase 45,417 shares of our common stock, at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Preferred Stock and Warrants of \$2,725,000. The shares of Series A Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share.

On January 14, 2008, we announced the signing of a definitive licensing agreement under which RHEI Pharmaceuticals, Inc. will market and manufacture MuGard in the Peoples Republic of China and certain Southeast Asian countries. RHEI will also obtain the necessary regulatory approvals for MuGard in the territory.

On January 4, 2008, we closed our acquisition of Somanta Pharmaceuticals, Inc. In connection with the acquisition, Access issued an aggregate of approximately 1.5 million shares of Access Pharmaceuticals, Inc. common stock to the common and preferred shareholders of Somanta as consideration. In addition, Access exchanged all outstanding warrants of Somanta for warrants to purchase 191,991 shares of Access common stock at exercise prices ranging between \$18.55 and \$69.57 per share.

In addition, \$1,576,000 of Somanta Pharmaceuticals’ acquired accounts payable were settled by issuing 538,508 shares of Access common stock and warrants to purchase 246,753 shares of Access common stock at an exercise price of \$3.50 per share. The value of the shares and warrants issued was determined based on the fair value of the accounts payable.

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

## **Patents**

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

Two U.S. patent applications and two European patent applications are under review 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.

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

Thiarabine is subject to two process patents that expire in 2018, one use patent that expires in 2019, as well as patent applications that provide additional protection to the manufacturing process and use.

In 2007, MacroChem acquired exclusive worldwide rights for drug uses of pexiganan, a novel, small peptide anti-infective for topical treatment of patients with mild diabetic foot infection (DFI) from Genaera Corporation (Genaera). Under the terms of the license agreement, Genaera was paid an initial fee of \$1 million through February 1, 2008. The deal terms also include payments of \$7 million to Genaera upon the achievement of certain clinical and regulatory milestones through approval, sales-based milestones of up to \$35 million, and 10% royalty payments on net sales. In addition, we assumed all clinical development, manufacturing and regulatory activities for pexiganan.

We own six composition of matter and use patents, with expiration dates ranging from 2015 to 2019, for the combination of SEPA with numerous existing classes of drugs, including antifungals and human sex hormones. The patent for SEPA combined with antifungals covers the combination of SEPA and econazole in EcoNail, and the patent for SEPA combined with human sex hormones covers the combination of SEPA and testosterone in Opterone.

With respect to Access' MacroDerm technology, we have three U.S. patents covering the chemical composition and use of the MacroDerm polymers, which expire in 2015.

In addition to the patent activity, we have trademarks for the marks SEPA, EcoNail, MacroDerm and Opterone.

We have 13 key use patents related to Phenylbutyrate which have been issued to the NIH and licensed to us.

We have two patented Cobalamin-mediated targeted therapeutic technologies:

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

We also have intellectual property in connection with the use of another B vitamin, folic acid, for targeting of polymer therapeutics. Enhanced tumor delivery is achieved by targeting folate receptors, which are upregulated in certain tumor types. We have two U.S. and two European patent applications related to folate polymer therapeutics.

We have two patents relating to composition and the humanization of Angiolix patents which expire in 2015.

We have one patent and one patent application which protects the composition of matter and use of Prodrax molecules. These will expire in 2023.

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

- Mucoadhesive technology in 2021,
- ProLindac™ in 2021,
- Thiarabine in 2018,
- Pexiganan in 2016,
- EcoNail in 2019,
- Phenylbutyrate between 2011 and 2016,
- Angiolix® in 2015,
- Prodrax in 2023,
- Cobalamin mediated technology between 2009 and 2019

In addition to issued patents, we have a number of pending patent applications. If issued, the patents underlying these applications could extend the patent life of our technologies beyond the dates listed above.

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**

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 New Drug Application ("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 1 the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages and in some indications such as cancer and HIV, as preliminary evidence of efficacy in humans. Phase 2 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 2, it is then evaluated in Phase 3 clinical trials. Phase 3 trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit to risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA for approval to commence commercial sales.

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

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

### **Competition**

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

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.

Amgen Inc., Carrington Laboratories Inc., CuraGen Corporation, Cytogen Corporation, Endo Pharmaceuticals, MGI Pharma Inc., Nuvelo, Inc. and OSI Pharmaceuticals Inc. are developing products to treat mucositis that may compete with Access' mucoadhesive liquid technology.

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 in the US; and
- Oxaliplatin, marketed exclusively by Sanofi-Aventis.

The following companies are working on therapies and formulations that may be competitive with Access' polymer platinate:

- Antigenics and Regulon are developing liposomal platinum formulations;
- Poniard Pharmaceuticals is developing both i.v. and oral platinum formulations;
- Nanocarrier and Debio are developing micellar nanoparticle platinum formulations; and
- American Pharmaceutical Partners, Cell Therapeutics, Daiichi, and Enzon are developing alternate drugs in combination with polymers and other drug delivery systems.

Thiarabine's competitors are Eli Lilly and Company, Bayer Healthcare, SciClone Pharmaceuticals and Genzyme.

With respect to mild diabetic foot infection (DFI), there is currently no topical treatment approved by the FDA. In addition, we are not aware of any other companies working on a topical treatment for mild diabetic foot infection.

With respect to onychomycosis, Novartis AG and Johnson & Johnson each offer an orally administered antifungal therapy and Sanofi Aventis (Dermik Laboratories) offers a topical nail lacquer therapy for treating fungal infections of the nail. A number of other companies, including Nexmed, Inc./Novartis AG, Schering-Plough/Anacor Pharmaceuticals, Inc. and Ivrea/MediQuest Therapeutics, Inc., are also developing topical therapies for these infections.

Companies working on therapies and formulations that may be competitive with our Sodium Phenylbutyrate are Medicis Pharmaceuticals which currently sells Sodium Phenylbutyrate (Buphenyl®) for the treatment of a urea cycle disorder, hyperuremia. We are aware of numerous products in development for brain cancers. We are aware of several products being developed by academic and commercial organizations targeting glioblastoma.

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

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

We are targeting a propriety gene product which is expressed by cancerous tumors. We are not aware of any other organization developing similar products targeting this type of protein.

Companies working on therapies and formulations that may be competitive with our Prodrax are Novocea, Inc., which has exclusively licensed from KuDOS Pharmaceuticals, a subsidiary of Astra Zeneca, a small molecule prodrug that is selectively activated by low oxygen tumors that is similar to our Prodrax, and Novocea is developing this small molecule prodrug in a similar fashion to Prodrax.

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 its joint efforts with collaborative partners therefore may not be commercially competitive with its competitors' existing products or products under development.

## Suppliers

Some materials used by us are specialized. We obtain materials from several suppliers based in different countries around the world. If materials are unavailable from one supplier we have alternate suppliers available.

## Employees

As of March 30, 2009, we had nine full time employees, four 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

We make available free of charge through our website, [www.accesspharma.com](http://www.accesspharma.com), our annual reports on Form 10-K and other reports that we file with the Securities and Exchange Commission as well as certain of our corporate governance policies, including the charters for the Board of Directors' audit, compensation and nominating and corporate governance committees and its code of ethics, corporate governance guidelines and whistleblower policy. We will also 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 us at: Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207 attn: Investor Relations.

## ITEM 1A. RISK FACTORS

### **Without obtaining adequate capital funding, we may not be able to continue as a going concern.**

The report of our independent registered public accounting firm for the fiscal year ended December 31, 2008 contained a fourth explanatory paragraph to reflect its significant doubt about our ability to continue as a going concern as a result of our history of losses and our liquidity position. If we are unable to obtain adequate capital funding in the future, we may not be able to continue as a going concern, which would have an adverse effect on our business and operations, and investors' investment in us may decline.

### **We have experienced a history of losses, we expect to incur future losses and we may be unable to obtain necessary additional capital to fund operations in the future.**

We have recorded minimal revenue to date and have incurred an accumulated deficit of approximately \$134.9 million through December 31, 2008. Net losses for the years ended 2008 and 2007 were \$20.6 million and \$36.7 million, 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. Our net cash burn rate for the year ended December 31, 2008 was approximately \$505,000 per month. We project our net cash burn rate from operations for the next twelve months to be approximately \$115,000 per month. Capital expenditures are forecasted to be minor for the next twelve months.

We require substantial capital for its development programs and operating expenses, to pursue regulatory clearances and to prosecute and defend its intellectual property rights. We believe that our existing capital resources, interest income, product sales, royalties and revenue from possible licensing agreements and collaborative agreements will be sufficient to fund our currently expected operating expenses and capital requirements into the first quarter of 2010. We will need to raise substantial additional capital to support our ongoing operations.

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

**We have issued and outstanding shares of Series A Preferred Stock with rights and preferences superior to those of our common stock.**

The issued and outstanding shares of Series A Preferred Stock grant the holders of such preferred stock anti-dilution, dividend and liquidations rights that are superior to those held by the holders of our common stock. Should we issue additional shares of common stock for a price below \$3.00 per share, the conversion price of the Series A Preferred Stock shall be lowered to the lowest issue price below \$3.00 per share which will have the effect of diluting the holders of our common stock.

**We do not have operating revenue and it may never attain profitability.**

To date, we have funded its operations primarily through private sales of common stock, preferred stock and convertible notes. Contract research payments and licensing fees from corporate alliances and mergers have also provided funding for its operations. Our ability to achieve significant revenue or profitability depends upon our ability to successfully complete the development of drug candidates, to develop and obtain patent protection and regulatory approvals for our drug candidates and to manufacture and commercialize the resulting drugs. We sold its only revenue producing assets to Uluru, Inc. in October 2005. We are not expecting any significant revenues in the short-term from its 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 its operations.

**Although we expect that the acquisition of MacroChem will result in benefits to the combined company the combined company may not realize those benefits because of integration and other challenges.**

Our ability to realize the anticipated benefits of the merger will depend, in part, on the ability of the Company to integrate the business of MacroChem with the business of Access. The combination of two independent companies is a complex, costly and time-consuming process. This process may disrupt the business of either or both of the companies, and may not result in the full benefits expected by Access and MacroChem. The difficulties of combining the operations of the companies include, among others:

- unanticipated issues in integrating information, communications and other systems;
- consolidating corporate and administrative infrastructures; and
- the diversion of management's attention from ongoing business concerns.

**We may not successfully commercialize our drug candidates.**

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

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

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

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

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

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

Our ability to successfully commercialize, and market our 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 its polymer platinate program, to date we have not entered into any licensing arrangement, other than for China and Korea. We may be unable to execute our licensing strategy for polymer platinate.

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

We have limited experience in the manufacture of pharmaceutical products in clinical quantities or for commercial purposes and we may not be able to manufacture any new pharmaceutical products that we may develop. As a result, we have established, and in the future intends 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 its finished pharmaceutical or other medical products, if any, market introduction and 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 its 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.

ProLindac™ is manufactured by third parties for Access' Phase 2 clinical trials. Manufacturing is ongoing for the current clinical trials. Certain manufacturing steps are conducted by us to enable significant cost savings to be realized.

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

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

- A mucoadhesive liquid technology product, MuGard™, has received marketing approval by the FDA.
- ProLindac™ is in the planning stage for a Phase 2 trial in China, Korea and Europe.
- ProLindac™ has been approved for an additional Phase 1 trial in the US by the FDA.
- Thiarabine is in the planning stage for a Phase 2 trial in the United States.
- Pexiganan clinical work will proceed with a commercial partner.
- EcoNail will proceed with a commercial partner.
- Phenylbutyrate is in planning stage for a Phase 2 trial in the United States.
- Cobalamin™ mediated delivery technology is currently in the pre-clinical phase.
- Angiolix® is currently in the pre-clinical phase.
- Prodrax® is currently in the pre-clinical phase.
- Access also has other products in the preclinical phase.

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

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

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

Before we can obtain regulatory approvals for the commercial sale of any of our potential drugs, the drug candidates will be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. Preclinical or clinical trials of any of our future drug candidates may not demonstrate the safety and efficacy of such drug candidates at all or to the extent necessary to obtain regulatory approvals. In this regard, for example, adverse side effects can occur during the clinical testing of a new drug on humans which may delay ultimate FDA approval or even lead it to terminate our efforts to develop the drug for commercial use. Companies in the biotechnology industry have suffered significant setbacks in advanced clinical trials, even after demonstrating promising results in earlier trials. In particular, polymer platinate has taken longer to progress through clinical trials than originally planned. This extra time has not been related to concerns of the formulations but rather due to the lengthy regulatory process. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate. A delay or failure to receive regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in its 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 its products for which we may be unable to obtain insurance coverage.**

Our business exposes it 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 its products that are used in clinical tests or marketed to the public. We generally procure product liability insurance for drug candidates that are undergoing human clinical trials. Product liability insurance for the biotechnology industry is generally expensive, if available at all, and as a result, we may be unable to obtain insurance coverage at acceptable costs or in a sufficient amount in the future, if at all. We may be unable to satisfy any claims for which we may be held liable as a result of the use or misuse of products which we have developed, manufactured or sold and any such product liability claim could adversely affect our business, operating results or financial condition.

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

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

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

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

Amgen Inc., Carrington Laboratories Inc., CuraGen Corporation, Cytogen Corporation, Endo Pharmaceuticals, MGI Pharma Inc., Nuvelo, Inc. and OSI Pharmaceuticals Inc. are developing products to treat mucositis that may compete with our mucoadhesive liquid technology.

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 in the US; and
- Oxaliplatin, marketed exclusively by Sanofi-Aventis.

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

- Antigenics and Regulon are developing liposomal platinum formulations;
- Poniard Pharmaceuticals is developing both i.v. and oral platinum formulations;
- Nanocarrier and Debio are developing micellar nanoparticle platinum formulations; and
  - American Pharmaceutical Partners, Cell Therapeutics, Daiichi, and Enzon are developing alternate drugs in combination with polymers and other drug delivery systems.

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Companies working on therapies and formulations that may be competitive with our Sodium Phenylbutyrate are Medicis Pharmaceuticals which currently sells Sodium Phenylbutyrate (Buphenyl<sup>®</sup>) for the treatment of a urea cycle disorder, hyperuremia. We are aware of numerous products in development for brain cancers. We are aware of several products being developed by academic and commercial organizations targeting glioblastoma.

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

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

We are targeting a propriety gene product which is expressed by cancerous tumors. We are not aware of any other organization developing similar products targeting this type of protein.

Companies working on therapies and formulations that may be competitive with our Prodrax are Novocea, Inc., which has exclusively licensed from KuDOS Pharmaceuticals, a subsidiary of Astra Zeneca, a small molecule prodrug that is selectively activated by low oxygen tumors that is similar to our Prodrax, and Novocea is developing this small molecule prodrug in a similar fashion to Prodrax.

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 its joint efforts with collaborative partners therefore may not be commercially competitive with its competitors' existing products or products under development.

**We depend on licenses from third parties and the maintenance of its licenses are necessary for our success.**

We, as a result of our recent acquisition of MacroChem Corporation, have obtained rights to some product candidates through license agreements with various third party licensors as follows:

- A license for Thiarabine was acquired from Southern Research Institute of Birmingham, Alabama.
- A license for Sodium Phenylbutyrate was acquired from the NIH. Thirteen key use patents have been issued to the NIH and licensed by us.

We, as a result of our acquisition of Somanta Pharmaceuticals, Inc. in January 2008, have obtained rights to some product candidates through license agreements with various third party licensors as follows:

- Exclusive Patent and Know-how Sub-license Agreement between Somanta and Immunodex, Inc. dated August 18, 2005, as amended;
- Patent and Know-how Assignment and License Agreement between Somanta and De Montfort University dated March 20, 2003;
- Patent and Know-how Assignment and License Option Agreement between Somanta and The School of Pharmacy, University of London dated March 16, 2004, as amended on September 21, 2005; and
- The Phenylbutyrate Co-Development and Sublicense Agreement between Somanta and Virium Pharmaceuticals, Inc. dated February 16, 2005, as amended.

We are dependent upon these licenses for our rights to develop and commercialize our product candidates. While we believe we are in compliance with our obligations under the licenses, certain licenses may be terminated or converted to non-exclusive licenses by the licensor if we breach, or have breached the terms of the license. We cannot guarantee you that the licenses will not be terminated or converted in the future.

While we expect that we will be able to continue to identify licensable product candidates or research suitable for licensing and commercialization by it, there can be no assurance that this will occur.

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

The successful commercialization of, and the interest of potential collaborative partners to invest in the development of its 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. Limited reimbursement for the cost of any drugs that we develop may reduce the demand for, or price of such drugs, which would hamper its ability to obtain collaborative partners to commercialize its drugs, or to obtain a sufficient financial return on its own manufacture and commercialization of any future drugs.

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

The drugs that we are attempting to develop may compete with a number of well-established drugs manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any drugs developed by it will depend on a number of factors, including the establishment and demonstration of the clinical efficacy and safety of its 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 its 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 its ability to profitably sell any drugs that we may develop.**

Lower prices for pharmaceutical products may result from:

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

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

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

Our success depends, in part, on our ability to obtain U.S. and foreign patent protection for our drug candidates and processes, preserve our trade secrets and operate our business without infringing the proprietary rights of third parties. Legal standards relating to the validity of patents covering pharmaceutical and biotechnological inventions and the scope of claims made under such patents are still developing and there is no consistent policy regarding the breadth of claims allowed in biotechnology patents. The patent position of a biotechnology firm is highly uncertain and involves complex legal and factual questions. We cannot assure you that any existing or future patents issued to, or licensed by, us will not subsequently be challenged, infringed upon, invalidated or circumvented by others. As a result, although we, together with our subsidiaries, are either the owner or licensee to 34 U.S. patents and to 10 U.S. patent applications now pending, and 5 European patents and 13 European patent applications, we cannot assure you that any additional patents will issue from any of the patent applications owned by, or licensed to, it. Furthermore, any rights that we may have under issued patents may not provide it 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:

- Mucoadhesive technology in 2021,
- ProLindac™ in 2021,
- Thiarabine in 2018,
- Pexiganan in 2016,
- EcoNail in 2019,
- Phenylbutyrate between 2011 and 2016,
- Angiolix® in 2015,
- Prodrax in 2023,
- Cobalamin mediated technology between 2009 and 2019

In addition to issued patents, we have a number of pending patent applications. If issued, the patents underlying these applications could extend the patent life of its technologies beyond the dates listed above.

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

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

We are highly dependent upon the efforts of its senior management and scientific team, including its President and Chief Executive Officer, Jeffrey B. Davis. The loss of the services of one or more of these individuals could delay or prevent the achievement of its research, development, marketing, or product commercialization objectives. While we have employment agreements with Jeffrey B. Davis, David P. Nowotnik, PhD its Senior Vice President Research and Development, and Stephen B. Thompson, its Vice President and Chief Financial Officer, their employment may be terminated by them or us at any time. Mr. Davis', Dr. Nowotnik's and Mr. Thompson's agreements expire within one year and are extendable each year on the anniversary date. We do not have employment contracts with its other key personnel. We do not maintain any "key-man" insurance policies on any of its key employees and we do not intend to obtain such insurance. In addition, due to the specialized scientific nature of its business, we are highly dependent upon our ability to attract and retain qualified scientific and technical personnel. In view of the stage of its development and its research and development programs, we have restricted its 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.

**An investment in our common stock may be less attractive because it is not traded on a recognized public market.**

Our common stock has traded on the OTC Bulletin Board, or OTCBB since June 5, 2006. From February 1, 2006 until June 5, 2006 we traded on the "Pink Sheets" after our common stock was de-listed from trading on AMEX. The OTCBB and Pink Sheets are viewed by most investors as a less desirable, and less liquid, marketplace. As a result, an investor may find it more difficult to purchase, dispose of or obtain accurate quotations as to the value of our common stock.

Our common stock is subject to Rules 15g-1 through 15g-9 under the Exchange Act, which imposes certain sales practice requirements on broker-dealers who sell its common stock to persons other than established customers and "accredited investors" (as defined in Rule 501(c) of the Securities Act). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. This rule adversely affects the ability of broker-dealers to sell our common stock and purchasers of its common stock to sell their shares of our common stock.

Additionally, our common stock is subject to SEC regulations applicable to "penny stock." Penny stock includes any non-NASDAQ equity security that has a market price of less than \$5.00 per share, subject to certain exceptions. The regulations require that prior to any non-exempt buy/sell transaction in a penny stock, a disclosure schedule proscribed by the SEC relating to the penny stock market must be delivered by a broker-dealer to the purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker-dealer and the registered representative and current price quotations for our common stock. The regulations also require that monthly statements be sent to holders of penny stock that disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements adversely affect the market liquidity of our common stock.

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

As calculated by the SEC rules of beneficial ownership, SCO Capital Partners LLC and affiliates, Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.), and Lake End Capital LLC each beneficially owned approximately 59.0%, 8.3% and 11.7%, respectively, of our common stock as of March 30, 2009. Accordingly, they collectively may have the ability to significantly influence or determine the election of all of our directors or the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of our other stockholders.

**We may be required to pay liquidated damages to certain investors if we do not maintain an effective registration statement relating to common stock issuable upon conversion of Series A Preferred stock or upon exercise of certain warrants.**

Pursuant to issuing Series A Preferred Stock and warrants, we entered into an Investor Rights Agreement with the purchasers of Series A Preferred Stock. The Investor Rights Agreement requires, among other things, that we maintain an effective registration statement for common stock issuable upon conversion of Series A Preferred Stock or upon exercise of certain warrants. If we fail to maintain such an effective registration statement it may be required to pay liquidated damages to the holders of such Series A Preferred Stock and warrants for the period of time in which an effective registration statement was not in place.

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

Provisions of our Certificate of Incorporation, By-laws and Stockholders Rights Plan may make it more difficult for a third party to acquire control of the Company, even if a change in control would benefit our stockholders. In particular, shares of our preferred stock may be issued in the future without further stockholder approval and upon such terms and conditions, and having such rights, privileges and preferences, as our Board of Directors may determine, including, for example, rights to convert into our common stock. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any of our preferred stock that may be issued in the future. The issuance of our preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire control of us. This could limit the price that certain investors might be willing to pay in the future for shares of our common stock and discourage these investors from acquiring a majority of our common stock. Further, the existence of these corporate governance provisions could have the effect of entrenching management and making it more difficult to change our management.

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

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

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

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 its stock price.

**Future sales by our stockholders could lower our stock price.**

Sales of our common stock in the public market could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all. Of the 11,315,272 shares of common stock outstanding as of March 30, 2009, 10,361,100 shares are, or will be, freely tradable without restriction, unless held by our "affiliates." Some of these shares may be resold under Rule 144. The sale of the 10,809,539 shares issuable upon conversion of our preferred stock and 9,687,326 shares issuable upon exercise of outstanding warrants could also lower the market price of our common stock.

## **ITEM 2. PROPERTIES**

Access maintains one facility of approximately 9,000 square feet for administrative offices and laboratories in Dallas, Texas. Access has a lease agreement for the facility, which terminates in December 2009. Adjacent space may be available for expansion which Access believes would accommodate growth for the foreseeable future.

Access believes that its existing properties are suitable for the conduct of its business and adequate to meet its present needs.

## **ITEM 3. LEGAL PROCEEDINGS**

The Company is not currently subject to any material pending legal proceedings.

## **ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not applicable.

## **EXECUTIVE OFFICERS OF THE REGISTRANT**

Mr. Jeffrey B. Davis, 46 has been our Chief Executive Officer since December 26, 2007. Previously, Mr. Davis was Chairman of the Board, member of the Executive Committee and a Chairman of the Compensation Committee of the Board. Mr. Davis currently serves as President of SCO Financial Group LLC. Previously, Mr. Davis served in senior management at a publicly traded healthcare technology company. Prior to that, Mr. Davis was an investment banker with various Deutsche Bank banking organizations, both in the U.S. and Europe. Mr. Davis also served in senior marketing and product management positions at AT&T Bell Laboratories, where he was also a member of the technical staff, and at Philips Medical Systems North America. Mr. Davis is currently on the board of Uluru, Inc.

David P. Nowotnik, Ph.D., 60, has been Senior Vice President Research and Development since January 2003 and was Vice President Research and Development from 1998. From 1994 until 1998, Dr. Nowotnik had been with Guilford Pharmaceuticals, Inc. in the position of Senior Director, Product Development and was responsible for a team of scientists developing polymeric controlled-release drug delivery systems. From 1988 to 1994 he was with Bristol-Myers Squibb researching and developing technetium radiopharmaceuticals and MRI contrast agents. From 1977 to 1988 he was with Amersham International leading the project which resulted in the discovery and development of Ceretec.

Mr. Phillip S. Wise, 51, has been our Vice President Business Development since June 1, 2006. Mr. Wise was Vice President of Commercial and Business Development for Enhance Pharmaceuticals, Inc. and Ardent Pharmaceuticals, Inc. from 2000 until 2006. Prior to that time he was with Glaxo Wellcome, from 1990 to 2000 in various capacities.

Mr. Stephen B. Thompson, 55, has been Vice President since 2000 and our Chief Financial Officer since 1996. From 1990 to 1996, he was Controller and Administration Manager of Access Pharmaceuticals, Inc., a private Texas corporation. Previously, from 1989 to 1990, Mr. Thompson was Controller of Robert E. Woolley, Inc. a hotel real estate company where he was responsible for accounting, finances and investor relations. From 1985 to 1989, he was Controller of OKC Limited Partnership, an oil and gas company where he was responsible for accounting, finances and SEC reporting. Between 1975 and 1985 he held various accounting and finance positions with Santa Fe International Corporation.

## PART II

### ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSURER PURCHASES OF EQUITY SECURITIES

#### Price Range of Common Stock and Dividend Policy

Our common stock has traded on the OTC Bulletin Board, or OTCBB, under the trading symbol ACCP since June 5, 2006. From February 1, 2006 until June 5, 2006, we traded on the "Pink Sheets" under the trading symbol AKCA. From March 30, 2000 until January 31, 2006, we traded on the American Stock Exchange, or AMEX, under the trading symbol AKC.

The following table sets forth, for the periods indicated, the high and low closing prices as reported by OTCBB for our common stock for fiscal years 2008 and 2007. The OTCBB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	Common Stock	
	High	Low
<b>Period Ended December 31, 2008</b>		
First quarter	\$ 3.50	\$ 1.35
Second quarter	3.30	1.40
Third quarter	3.49	2.50
Fourth quarter	2.75	0.80
<b>Fiscal Year Ended December 31, 2007</b>		
First quarter	\$ 10.66	\$ 2.50
Second quarter	6.75	4.30
Third quarter	5.16	2.10
Fourth quarter	4.48	2.10

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

We are required, however, to pay dividends on our preferred stock at the rate of 6% per year.

The number of record holders of Access common stock at March 30, 2009 was approximately 10,900. On March 30, 2009, the closing price for the common stock as quoted on the OTCBB was \$1.53. There were 11,315,272 shares of common stock outstanding at March 30, 2009.

## Equity Compensation Plan Information

The following table sets forth information as of December 31, 2008 about shares of Common Stock outstanding and available for issuance under our existing equity compensation plans.

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options warrants and rights</u>	<u>Weighted-average exercise price of outstanding options warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
Equity compensation plans approved by security holders			
2005 Equity Incentive Plan	1,136,820	\$ 1.90	1,956,644
1995 Stock Awards Plan	118,000	15.14	-
2001 Restricted Stock Plan	-	-	52,818
Equity compensation plans not approved by security holders			
2007 Special Stock Option Plan	100,000	2.90	350,000
Total	<u>1,354,820</u>	<u>\$ 3.12</u>	<u>2,359,462</u>

### The 2007 Special Stock Option Plan

The 2007 Special Stock Option Plan (the "Plan") was adopted by the Board in January 2007. The Plan is not intended to be an incentive stock option plan within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"). The Plan allows for the issuance of options to acquire up to 450,000 shares of our common stock of which 100,000 have been issued. The purpose of the Plan is to encourage ownership of Common Stock by employees, consultants, advisors and directors of Access and its affiliates and to provide additional incentive for them to promote the success of Access' business. The Plan provides for the grant of non-qualified stock options to employees (including officers, directors, advisors and consultants). The Plan will expire in January 2017, unless earlier terminated by the Board. The options in the Plan granted to date expire March 12, 2010.

### Issuer Purchases of Equity Securities

None

## ITEM MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND

7.

### RESULTS OF OPERATIONS

The following discussion should be read in conjunction with our consolidated financial statements and related notes included in this Form 10-K.

Access Pharmaceuticals, Inc. (together with our subsidiaries, "We", "Access" or the "Company") is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one approved product, one product at Phase 3 of clinical development, four products in Phase 2 of clinical development and four products in pre-clinical development. Our description of our business, including our list of products and patents, takes into consideration our acquisition of MacroChem Corporation which closed February 25, 2009.

#### Results of Operations

##### Comparison of Years Ended December 31, 2008 and 2007

Our licensing revenue for the year ended December 31, 2008 was \$118,000 as compared to \$23,000 for 2007, an increase of \$95,000. We received upfront licensing payments from SpePharm, RHEI, Milestone and ASK in 2007 and 2008. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We have a sponsored research and development agreement. Our revenue from this agreement for the year ended December 31, 2008 was \$173,000 as compared to \$34,000 for 2007, an increase of \$139,000. We recognize revenue over the term of the agreement as services are performed. The agreement started in December 2007 and was completed in the third quarter of 2008.

Total research and development spending for the year ended December 31, 2008 was \$12,613,000, as compared to \$2,602,000 for 2007, an increase of \$10,011,000. The increase in expenses was primarily due to:

- the Somanta acquisition resulted in a one-time non-cash in-process research and development expense in the first quarter of 2008 (\$8,879,000);
- costs for product manufacturing for a new ProLindac clinical trial expected to start in early 2009 (\$548,000);
- higher scientific consulting expenses (\$278,000);
- higher salary and related cost due to the hiring of additional scientific staff (\$269,000); and
- other net increases in research spending (\$86,000);
- partially offset by lower clinical development costs (\$49,000) due to the winding down of the ProLindac Phase 2 clinical trial.

Total general and administrative expenses were \$4,340,000 for 2008, an increase of \$264,000 over 2007 expenses of \$4,076,000. The increase in spending was due primarily to the following:

- accrual of potential liquidated damages under an investor rights agreement with certain investors (\$675,000);
- higher patent expenses and license fees (\$453,000);
- higher professional fees (\$29,000);
- lower salary and other salary related expenses (\$469,000);
- lower salary related expenses due to stock option expenses (\$325,000);
- lower investor relations expenses (\$148,000); and
- other net increases in general and administrative expenses (\$49,000).

Depreciation and amortization was \$253,000 for the year ended December 31, 2008, as compared to \$279,000 for 2007 reflecting a decrease of \$26,000. The decrease in depreciation and amortization was due to certain assets becoming fully depreciated.

Total operating expenses for the year ended December 31, 2008, were \$17,206,000 as compared to total operating expenses of \$6,957,000 for same period in 2007, an increase of \$10,249,000.

Interest and miscellaneous income was \$178,000 for the year ended December 31, 2008, as compared to \$125,000 for 2007, an increase of \$53,000. The increase in interest and miscellaneous income was due higher average cash balances during 2008 versus 2007.

Interest and other expense was \$478,000 for the year ended December 31, 2008, as compared to \$3,514,000 in 2007, a decrease of \$3,036,000. The decrease in interest and other expense was due to amortization of the discount on certain convertible notes and the amortization of certain additional notes recognized in 2007. In addition, the decrease in interest and other expense was due to \$9,015,000 of convertible notes that were outstanding until November 7, 2007, that were not outstanding during 2008. The convertible notes were exchanged for preferred stock in November 2007.

Convertible notes payable of \$10,015,000 and accrued interest of \$1,090,000 were converted from debt and accrued interest payable into preferred stock on November 10, 2007. A conversion of portion of the debt and interest resulted in a loss on the extinguishment of debt of \$11,628,000 for 2007. There was no conversion of debt or interest in 2008. The same transaction in November 2007 also resulted in a beneficial conversion feature that was recorded as preferred stock dividends of \$14,648,000.

An additional \$451,000 in preferred stock dividends was recorded in the first quarter of 2008. The change was due to preferred stock dividends and the beneficial conversion feature associated with the warrants issued in association with the sale of preferred stock in November 2007.

On February 4, 2008, we issued 272.5 shares of our Series A Preferred Stock. The shares are convertible into common stock at \$3.00 per share. Based on the price of our common stock on February 4, 2008, a new conversion price was calculated for accounting purposes for the Series A Preferred Stock and was considered to be "in the money" at the time of the agreement to exchange the convertible notes for preferred stock. This resulted in a beneficial conversion feature. The preferred stockholder has the right at any time to convert all or any lesser portion of the Series A Preferred Stock into common stock. This resulted in an intrinsic value of the preferred stock. The difference between the implied value of the preferred stock and the beneficial conversion feature was treated as preferred stock dividends of \$857,000 for the year ended December 31, 2008.

Preferred stock dividends of \$2,050,000 were accrued for the year ended December 31, 2008 and \$260,000 for 2007, an increase of \$1,790,000. Preferred stock was first issued in November 2007. Dividends are paid semi-annually in either cash or common stock.

We recognized deferred revenues of \$173,000 from discontinued operations in 2007. There were no discontinued operations recognitions in 2008.

Net loss allocable to common stockholders for the year ended December 31, 2008, was \$20,573,000, or a \$3.51 basic and diluted loss per common share, compared with a loss of \$36,652,000, or a \$10.32 basic and diluted loss per common share for 2007, a decreased loss of \$16,079,000.

### **Liquidity and Capital Resources**

We have funded our operations primarily through private sales of common stock, preferred stock, convertible notes and through licensing agreements. Our principal source of liquidity is cash and cash equivalents. Licensing fees provided minimal funding for operations during the year ended December 31, 2008. As of March 30, 2009, our cash and cash equivalents were \$2,289,000 and our net cash burn rate for the year ended December 31, 2008, was approximately \$505,000 per month. As of December 31, 2008, our working capital deficit was \$1,356,000. Our working capital at December 31, 2008 represented a decrease of \$7,595,000 as compared to our working capital as of December 31, 2007 of \$6,239,000. The decrease in working capital at December 31, 2008 reflects the net capital raised in the February private placement of \$2,444,000 and new licensing agreements with RHEI, ASK and Milestone, offset by operating expenses which included manufacturing product scale-up for our new ProLindac trial and Somanta expenses. Also included in the decrease are an estimated \$1,896,000 in dividends and interest due the Series A Preferred Shareholders which we anticipate will be paid in shares of Access common stock and not in cash. As of December 31, 2008, we had one convertible note outstanding in the principle amount of \$5.5 million which is due September 13, 2011.

As of March 30, 2009, the Company did not have enough capital to achieve its long-term goals. If we raise additional funds by selling equity securities, the relative equity ownership of our existing investors would be diluted and the new investors could obtain terms more favorable than previous investors. A failure to obtain necessary additional capital in the future could jeopardize our operations.

We have generally incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of December 31, 2008 of \$134,897,000. We expect that our capital resources will be adequate to fund our current level of operations into the first quarter of 2010. However, our ability to fund operations over this time could change significantly depending upon changes to future operational funding obligations or capital expenditures. As a result we may be required to seek additional financing sources within the next twelve months. We cannot assure you that we will ever be able to generate significant product revenue or achieve or sustain profitability.

All shares and per share information reflect a one for five reverse stock split effected June 5, 2006.

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

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

- the successful development and commercialization of ProLindac™, MuGard™ and our other product candidates;
- the ability to convert, repay or restructure our outstanding convertible notes and debentures;
- the ability to integrate MacroChem Corporation assets and programs with ours;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- successful regulatory filings.

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

(in thousands) Project	Twelve Months ended December 31,		Inception To Date (1)
	2008	2007	
Polymer Platinite (ProLindac™)	\$ 3,402	\$ 2,563	\$ 25,619
Mucoadhesive Liquid Technology (MLT)	-	21	1,511
Angiolix	268	-	268
Others (2)	64	18	5,126
Total	<u>\$ 3,734</u>	<u>\$ 2,602</u>	<u>\$ 32,524</u>

(1) Cumulative spending from inception of the Company or project through December 31, 2008.

(2) Includes: Vitamin Mediated Targeted Delivery, carbohydrate targeting, amlexanox cream and gel and other related projects.

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

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

#### Critical Accounting Policies and Estimates

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

#### Asset Impairment

Our intangible assets at December 31, 2008 consist primarily of patents acquired in acquisitions and licenses which were recorded at fair value on the acquisition date. We perform an impairment test on at least an annual basis or when indications of impairment exist. At December 31, 2008, Management believes no impairment of our intangible assets exists.

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

## Revenues

Our revenues are generated from licensing and research and development agreements. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104), *Revenue Recognition*. License revenue is recognized over the remaining life of the underlying patent. Research and development revenues are recognized as services are performed.

## Stock Based Compensation Expense

On January 1, 2006, we adopted SFAS No. 123 (revised 2004), "*Share-Based Payment*," ("SFAS 123(R)"), which requires the measurement and recognition of all share-based payment awards made to employees and directors including stock options based on estimated fair values. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board ("APB") Opinion No. 25, "*Accounting for Stock Issued to Employees*" ("APB 25"), for periods beginning in fiscal year 2006. In March 2005, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 107 ("SAB 107") relating to SFAS 123(R). We applied the provisions of SAB 107 in its adoption of SFAS 123(R).

We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's 2006 fiscal year. Our consolidated financial statements for the years ended December 31, 2007 and 2006, reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our consolidated financial statements for prior periods have not been restated to include the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the years ended December 31, 2008 and 2007 was approximately \$415,000 and \$1,048,000, respectively.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service period in the company's Statement of Operations. Prior to the adoption of SFAS 123(R), we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB No. 25 as allowed under SFAS No. 123, "*Accounting for Stock-Based Compensation*" ("SFAS 123"). Under the intrinsic value method, no stock-based compensation expense for stock option grants was recognized because the exercise price of our stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant. There were no restricted stock awards granted in either 2007 or 2008 ..

Stock-based compensation expense recognized in the our Statement of Operations for the years ended December 31, 2008 and 2007 includes compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). Stock-based compensation expense recognized in the Company's Statement of Operations for the year ended December 31, 2008 and 2007 is based on awards ultimately expected to vest and has been reduced for estimated forfeitures, which currently is nil. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

We used the Black-Scholes option-pricing model ("Black-Scholes") as our method of valuation under SFAS 123(R) in fiscal years 2008 and 2007 and a single option award approach. This fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. The fair value of share-based payment awards on the date of grant as determined by the Black-Scholes model is affected by our stock price as well as other assumptions. These assumptions include, but are not limited to the expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors.

## Accounting for Uncertain Tax Positions

As of January 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109, Accounting for Income Taxes* (“FIN 48”). The adoption did not have a material impact on our consolidated financial statements or effective tax rate and did not result in any unrecognized tax benefits. Interest costs and penalties related to income taxes are classified as interest expense and general and administrative costs, respectively, in our consolidated financial statements. For the years ended December 31, 2008 and 2007, we did not recognize any interest or penalty expense related to income taxes. It is determined not to be reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 12 months. We are currently subject to a three year statute of limitations by major tax jurisdictions. We and our subsidiaries file income tax returns in the U.S. federal jurisdiction.

## Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standard (“SFAS”) No. 157, “Fair Value Measurements” (“SFAS 157”). SFAS 157 defines fair value, establishes a market-based framework or hierarchy for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is applicable whenever another accounting pronouncement requires or permits assets and liabilities to be measured at fair value. SFAS 157 does not expand or require any new fair value measures; however the application of this statement may change current practice. The requirements of SFAS 157 became effective for our fiscal year 2008. However, in February 2008 the FASB decided that an entity need not apply this standard to nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis until the subsequent year. Accordingly, our adoption of this standard on January 1, 2008 was limited to financial assets and liabilities and did not have a material effect on our financial condition or results of operations. We are still in the process of evaluating this standard with respect to its effect on nonfinancial assets and liabilities and therefore have not yet determined the impact that it will have on our financial statements upon full adoption.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), “Business Combinations” (“SFAS 141(R)”) and SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51” (“SFAS 160”). SFAS 141(R) will significantly change current practices regarding business combinations. Among the more significant changes, SFAS 141(R) expands the definition of a business and a business combination; requires the acquirer to recognize the assets acquired, liabilities assumed and noncontrolling interests (including goodwill), measured at fair value at the acquisition date; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; requires assets acquired and liabilities assumed from contractual and noncontractual contingencies to be recognized at their acquisition-date fair values with subsequent changes recognized in earnings; and requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset. SFAS 160 will change the accounting and reporting for minority interests, reporting them as equity separate from the parent entity’s equity, as well as requiring expanded disclosures. SFAS 141(R) and SFAS 160 are effective for financial statements issued for fiscal years beginning after December 15, 2008. We are currently assessing the impact that SFAS 141(R) and SFAS 160 will have on our results of operations and financial position.

## Off-Balance Sheet Transactions

None

## Contractual Obligations

The Company’s contractual obligations as of December 31, 2008 are set forth below.

	Payment Due by Period		
	Total	Less Than 1 Year	1-4 Years
Long-Term Debt Obligations	\$ 5,500,000	\$ -	\$ 5,500,000
Interest	1,271,000	424,000	847,000
Lease Obligations	106,000	87,000	19,000
Total	<u>\$ 6,877,000</u>	<u>\$ 511,000</u>	<u>\$ 6,366,000</u>

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

Financial statements required by this Item are incorporated in this Form 10-K on pages F-1 through F-21. Reference is made to Item 15 of this Form -10-K.

## **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

None

## **ITEM 9A(T). CONTROLS AND PROCEDURES**

Under the supervision and with the participation of our management, including the Chief Executive Officer and Chief Financial Officer, we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report.

### **Evaluation of Disclosure Controls and Procedures**

We conducted an evaluation of the effectiveness of the design and operation of our “disclosure controls and procedures” (Disclosure Controls) as of the end of the period covered by this Form 10-K. The controls evaluation was conducted under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer. Disclosure Controls are controls and procedures designed to reasonably assure that information required to be disclosed in our reports filed under the Exchange Act, such as this Form 10-K, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission’s (SEC’s) rules and forms. Disclosure Controls are also designed to reasonably assure that such information is accumulated and communicated to our management, including the Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

The evaluation of our Disclosure Controls included a review of the controls’ objectives and design, our implementation of the controls and the effect of the controls on the information generated for use in this Form 10-K. During the course of our evaluation of our internal control over financial reporting, we advised the Audit Committee of our Board of Directors that we had identified a material weakness as defined under standards established by the Public Company Accounting Oversight Board (United States). A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company’s annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness we identified is discussed in “Management’s Report on Internal Control Over Financial Reporting” below. Our Chief Executive Officer and Chief Financial Officer have concluded that as a result of the material weakness, as of the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures were not effective.

### **Management’s Report on Internal Control Over Financial Reporting**

“Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our internal control system was designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes, in accordance with generally accepted accounting principles. Because of inherent limitations, a system of internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate due to change in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management, including our principal executive officer and principal accounting officer, conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework.

Based on its evaluation, our management concluded that there is a material weakness in our internal control over financial reporting. The material weakness identified did not result in the restatement of any previously reported financial statements or any related financial disclosure, nor does management believe that it had any effect on the accuracy of the Company's financial statements for the current reporting period. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness relates to the monitoring and review of work performed by our Chief Financial Officer in the preparation of audit and financial statements, footnotes and financial data provided to the Company's registered public accounting firm in connection with the annual audit. All of our financial reporting is carried out by our Chief Financial Officer. This lack of accounting staff results in a lack of segregation of duties and accounting technical expertise necessary for an effective system of internal control.

In order to mitigate this material weakness to the fullest extent possible, all financial reports are reviewed by the Chief Executive Officer as well as the Chairman of the Audit Committee for reasonableness. All unexpected results are investigated. At any time, if it appears that any control can be implemented to continue to mitigate such weaknesses, it is immediately implemented. As soon as our finances allow, we will hire sufficient accounting staff and implement appropriate procedures for monitoring and review of work performed by our Chief Financial Officer.

Because of the material weakness described above, management concluded that, as of December 31, 2008, our internal control over financial reporting was not effective based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management's report in this annual report.

This report shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that section, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing."

#### Changes In Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2008 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

#### **ITEM 9B. OTHER INFORMATION**

None.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

**Directors and Reports of Beneficial Ownership.** The information required by this Item is incorporated herein by reference from the information to be contained in our 2009 Proxy Statement to be filed with the U.S. Securities and Exchange Commission in connection with the solicitation of proxies for our Annual Meeting of Shareholders to be held on May 27, 2009 (the Proxy Statement). The information under the heading “Executive Officers of the Registrant” in Part I of this Form 10-K is also incorporated by reference.

**Code of Ethics.** We have adopted a Code of Business Conduct and Ethics (the “Code”) that applies to all of our employees (including executive officers) and directors. The Code is available on our website at [www.accesspharma.com](http://www.accesspharma.com) under the heading “Investor Information”. We intend to satisfy the disclosure requirement regarding any waiver of a provision of the Code applicable to any executive officer or director, by posting such information on such website. Access shall provide to any person without charge, upon request, a copy of the Code. Any such request must be made in writing to Access, c/o Investor Relations, 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207.

Our corporate governance guidelines and the charters of the audit committee, compensation committee and nominating and corporate governance committee of the Board of Directors are available on our website at [www.accesspharma.com](http://www.accesspharma.com) under the heading “Investor Information”. Access shall 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, c/o Investor Relations, 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207.

### ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be contained in the Proxy Statement and is incorporated herein by reference.

## ITEM 15. EXHIBITS

### Page

a. Financial Statements. The following financial statements are submitted as part of this report:

Report of Registered Independent Public Accounting Firm	F-1
Consolidated Balance Sheets at December 31, 2008 and 2007	F-2
Consolidated Statements of Operations for 2008 and 2007	F-3
Consolidated Statements of Stockholders' Equity (Deficit) for 2008 and 2007	F-4
Consolidated Statements of Cash Flows for 2008 and 2007	F-5
Notes to Consolidated Financial Statements	F-6

### b. Exhibits

- 2.1 Amended and Restated Agreement of Merger and Plan of Reorganization between the Registrant and Chemex Pharmaceuticals, Inc., dated as of October 31, 1995 (Incorporated by reference to Exhibit A of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
- 2.2 Agreement and Plan of Merger, by and among the Registrant, Somanta Acquisition Corporation, Somanta Pharmaceuticals, Inc., Somanta Incorporated and Somanta Limited, dated April 19, 2007 (Incorporated by reference to Exhibit 2.1 to our Form 8-K dated April 18, 2007)
- 2.3 Agreement and Plan of Merger, by and among the Registrant, MACM Acquisition Corporation and MacroChem Corporation, dated July 9, 2008 (Incorporated by reference to Exhibit 2.3 of our Form 10-Q for the quarter ended June 30, 2008)
- 3.1 Certificate of Incorporation (Incorporated by reference to Exhibit 3(a) of our Form 8-K dated July 12, 1989, Commission File Number 9-9134)
- 3.2 Certificate of Amendment of Certificate of Incorporation filed August 13, 1992 (Incorporated by reference to Exhibit 3.3 of our Form 10-K for year ended December 31, 1995)
- 3.3 Certificate of Merger filed January 25, 1996 (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
- 3.4 Certificate of Amendment of Certificate of Incorporation filed January 25, 1996 (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
- 3.5 Certificate of Amendment of Certificate of Incorporation filed July 18, 1996 (Incorporated by reference to Exhibit 3.7 of our Form 10-K for the year ended December 31, 1996)
- 3.6 Certificate of Amendment of Certificate of Incorporation filed June 18, 1998. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended June 30, 1998)
- 3.7 Certificate of Amendment of Certificate of Incorporation filed July 31, 2000 (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended March 31, 2001)
- 3.8 Certificate of Designations of Series A Junior Participating Preferred Stock filed November 7, 2001 (Incorporated by reference to Exhibit 4.1.H of our Registration Statement on Form S-8 dated December 14, 2001, Commission File No. 333-75136)
- 3.9 Amended and Restated Bylaws (Incorporated by reference to Exhibit 2.1 of our Form 10-Q for the quarter ended June 30, 1996)
- 3.10 Certificate of Designation, Rights and Preferences of Series A Cumulative Convertible Preferred Stock filed November 9, 2007 (Incorporated by reference to Exhibit 3.10 to our Form SB-2 filed on December 10, 2007.
- 3.11 Certificate of Amendment to Certificate of Designations, Rights and Preferences of Series A Cumulative Convertible Preferred Stock filed June 11, 2008 (Incorporated by reference to Exhibit 3.11 of our Form 10-Q for the quarter ended June 30, 2008)
- 10.1\* 1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
- 10.2\* Amendment to 1995 Stock Option Plan (Incorporated by reference to Exhibit 10.25 of our Form 10-K for the year ended December 31, 2001)

- 10.3 Lease Agreement between Pollock Realty Corporation and the Registrant dated July 25, 1996 (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended September 30, 1996)
- 10.4 Platinate HPMA Copolymer Royalty Agreement between The School of Pharmacy, University of London and the Registrant dated November 19, 1996 (Incorporated by reference to Exhibit 10.9 of our Form 10-K for the year ended December 31, 1996)
- 10.5\* Employment Agreement of David P. Nowotnik, PhD (Incorporated by reference to Exhibit 10.19 of our Form 10-K for the year ended December 31, 1999)
- 10.6\* 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10-K for the year ended December 31, 1999)
- 10.7 Form of Convertible Note (Incorporated by reference to Exhibit 25 of our Form 10-Q for the quarter ended September 30, 2000)
- 10.8 Rights Agreement dated as of October 31, 2001 between the Registrant and American Stock Transfer & Trust Company, as Rights Agent (Incorporated by reference to Exhibit 99.1 of our Current Report on Form 8-K dated November 7, 2001)
- 10.9 Amendment to Rights Agreement dated as of February 16, 2006 between the Registrant and American Stock Transfer & Trust Company, as Rights Agent (Incorporated by reference to Exhibit 10.33 of our Form 10-Q for the quarter ended March 31, 2006)
- 10.10 Amendment to Rights Agreement dated as of November 9, 2007 between the Registrant and American Stock Transfer & Trust Company as Rights Agent
- 10.11\* 2001 Restricted Stock Plan (Incorporated by reference to Exhibit 1 of our Proxy Statement filed on April 16, 2001)
- 10.12\* 2005 Equity Incentive Plan (Incorporated by reference to Exhibit 1 of our Proxy Statement filed on April 18, 2005)
- 10.13\* Employment Agreement dated as of June 1, 2005, by and between the Registrant and Stephen B. Thompson (Incorporated by reference to Exhibit 10.24 of our 10-K for the year ended December 31, 2005)
- 10.14 Asset Sale Agreement dated as of October 12, 2005, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.25 of our 10-K for the year ended December 31, 2005)
- 10.15 Amendment to Asset Sale Agreement dated as of December 8, 2006, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.16 of our Form 10-KSB filed on April 2, 2007)
- 10.16 License Agreement dated as of October 12, 2005, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.26 of our 10-K for the year ended December 31, 2005)
- 10.17 Form of Warrant dated February 16, 2006, issued by the Registrant to certain Purchasers (Incorporated by reference to Exhibit 10.31 of our Form 10-Q for the quarter ended March 31, 2006)
- 10.18 Form of Warrant dated October 24, 2006, issued by the Registrant to certain Purchasers (Incorporated by reference to Exhibit 10.27 of our Form 10-KSB filed on April 2, 2007)
- 10.19 Form of Warrant December 6, 2006, issued by the Registrant to certain Purchasers (Incorporated by reference to Exhibit 10.32 of our Form 10-KSB filed on April 2, 2007)
- 10.20\* 2007 Special Stock Option Plan and Agreement dated January 4, 2007, by and between the Registrant and Stephen R. Seiler, President and Chief Executive Officer (Incorporated by reference to Exhibit 10.35 of our Form 10-QSB filed on May 15, 2007)
- 10.21 Note Purchase Agreement dated April 26, 2007, between the Registrant and Somanta Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.42 of our Form 10-Q filed on August 14, 2007)
- 10.22 Preferred Stock and Warrant Purchase Agreement, dated November 7, 2007, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.23 of our Form S-1 filed on March 11, 2008)
- 10.23 Investor Rights Agreement dated November 10, 2007, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.24 of our Form S-1 filed on March 11, 2008)
- 10.24 Form of Warrant Agreement dated November 10, 2007, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.25 of our Form S-1 filed on March 11, 2008)
- 10.25 Board Designation Agreement dated November 15, 2007, between the Registrant and SCO Capital Partners LLC (Incorporated by reference to Exhibit 10.26 of our Form S-1 filed on March 11, 2008)
- 10.26 Amendment and Restated Purchase Agreement, dated February 4, 2008 between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.27 of our Form S-1 filed on March 11, 2008)
- 10.27 Amended and Restated Investor Rights Agreement, dated February 4, 2008, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.28 of our Form S-1 filed on March 11, 2008)
- 10.28\* Employment Agreement dated January 4, 2008, between the Registrant and Jeffrey B. Davis (Incorporated by reference to Exhibit 10.29 of our Form S-1 filed on March 11, 2008)

- 21 Subsidiaries of the Registrant
- 23.1 Consent of Whitley Penn LLP
- 31.1 Chief Executive Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Chief Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32 Chief Executive Officer Certification Chief Financial Officer Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

\* Management contract or compensatory plan required to be filed as an Exhibit to this Form pursuant to Item 15(c) of the report.



## Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of  
Access Pharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Access Pharmaceuticals, Inc. and subsidiaries, as of December 31, 2008 and 2007, and the related consolidated statements of operations, changes in stockholders' equity (deficit), and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position Access Pharmaceuticals, Inc. and subsidiaries as of December 31, 2008 and 2007, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has had recurring losses from operations, negative cash flows from operating activities and has an accumulated deficit. Management's plans in regard to these matters are also described in Note 2. These conditions raise substantial doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

/s/ WHITLEY PENN LLP

Dallas, Texas  
March 31, 2009

**Access Pharmaceuticals, Inc. and Subsidiaries**

CONSOLIDATED BALANCE SHEETS

ASSETS	December 31, 2008	December 31, 2007
Current assets		
Cash and cash equivalents	\$ 2,663,000	\$ 6,921,000
Receivables	147,000	35,000
Receivables due from MacroChem Corp.	635,000	-
Receivables due from Somanta Pharmaceuticals, Inc.	-	931,000
Prepaid expenses and other current assets	105,000	410,000
Total current assets	3,550,000	8,297,000
Property and equipment, net	87,000	130,000
Patents, net	542,000	710,000
Other assets	78,000	12,000
Total assets	\$ 4,257,000	\$ 9,149,000
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	\$ 1,970,000	\$ 1,506,000
Accrued expenses	748,000	30,000
Dividends payable	1,896,000	260,000
Accrued interest payable	128,000	130,000
Current portion of deferred revenue	164,000	68,000
Current portion of convertible long-term debt	-	64,000
Total current liabilities	4,906,000	2,058,000
Long-term deferred revenue	2,245,000	910,000
Long-term convertible debt	5,500,000	5,500,000
Total liabilities	12,651,000	8,468,000
Commitments and contingencies		
Stockholders' equity (deficit)		
Convertible preferred stock - \$.01 par value; authorized 2,000,000 shares; 3,242,8617 issued at December 31, 2008; 3,227.3617 issued at December 31, 2007	-	-
Common stock - \$.01 par value; authorized 100,000,000 shares; issued, 6,967,474 at December 31, 2008; issued 3,585,458 at December 31, 2007	70,000	36,000
Additional paid-in capital	127,482,000	116,018,000
Notes receivable from stockholders	(1,045,000)	(1,045,000)
Treasury stock, at cost – 163 shares	(4,000)	(4,000)
Accumulated deficit	(134,897,000)	(114,324,000)
Total stockholders' equity (deficit)	(8,394,000)	681,000
Total liabilities and stockholders' equity (deficit)	\$ 4,257,000	\$ 9,149,000

The accompanying notes are an integral part of these consolidated statements.

**Access Pharmaceuticals, Inc. and Subsidiaries**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	December 31,	
	2008	2007
Revenues		
License revenues	\$ 118,000	\$ 23,000
Sponsored research and development	173,000	34,000
Total revenues	291,000	57,000
Expenses		
Research and development	12,613,000	2,602,000
General and administrative	4,340,000	4,076,000
Depreciation and amortization	253,000	279,000
Total expenses	17,206,000	6,957,000
Loss from operations	(16,915,000)	(6,900,000)
Interest and miscellaneous income	178,000	125,000
Interest and other expense	(478,000)	(3,514,000)
Loss on extinguishment of debt	-	(11,628,000)
	(300,000)	(15,017,000)
Loss before discontinued operations and before tax benefit	(17,215,000)	(21,917,000)
Income tax benefit	-	61,000
Loss from continuing operations	(17,215,000)	(21,856,000)
Less preferred stock dividends	(3,358,000)	(14,908,000)
Loss from continuing operations allocable to common stockholders	(20,573,000)	(36,764,000)
Discontinued operations, net of taxes of \$0 in 2008 and \$61,000 in 2007	-	112,000
Net loss allocable to common stockholders	\$ (20,573,000)	\$ (36,652,000)
Basic and diluted loss per common share		
Loss from continuing operations allocable to common stockholders	\$ (3.51)	\$ (10.35)
Discontinued operations	-	0.03
Net loss allocable to common stockholders	\$ (3.51)	\$ (10.32)
Weighted average basic and diluted common shares outstanding	5,854,031	3,552,006

The accompanying notes are an integral part of these consolidated statements.

**Access Pharmaceuticals, Inc. and Subsidiaries**

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Common Stock		Preferred Stock		Additional paid-in capital	Notes receivable from stockholders	Treasury stock	Accumulated deficit
	Shares	Amount	Shares	Amount				
Balance, December 31, 2006	3,535,000	\$ 35,000	-	\$ -	\$ 68,799,000	\$ (1,045,000)	\$ (4,000)	\$ (77,672,000)
Common stock issued for services	19,000	-	-	-	83,000	-	-	-
Options exercised	31,000	1,000	-	-	35,000	-	-	-
Stock option compensation expense	-	-	-	-	1,048,000	-	-	-
Preferred stock issuances	-	-	954.0001	-	5,560,000	-	-	-
Warrants issued with preferred stock	-	-	-	-	3,980,000	-	-	-
Costs of stock issuances	-	-	-	-	(868,000)	-	-	-
Beneficial conversion feature	-	-	-	-	14,648,000	-	-	-
Preferred stock dividend beneficial conversion	-	-	-	-	-	-	-	(14,648,000)
Conversion of convertible debt into preferred stock	-	-	2,273.3616	-	6,472,000	-	-	-
Warrants issued with preferred stock	-	-	-	-	4,633,000	-	-	-
Loss on extinguishment of debt – preferred stock	-	-	-	-	6,777,000	-	-	-
Loss on extinguishment of debt – warrants	-	-	-	-	4,851,000	-	-	-
Preferred dividends	-	-	-	-	-	-	-	(260,000)
Net loss	-	-	-	-	-	-	-	(21,744,000)
Balance, December 31, 2007	3,585,000	36,000	3,227.3617	-	116,018,000	(1,045,000)	(4,000)	(114,324,000)
Common stock issued for services	10,000	-	-	-	27,000	-	-	-
Warrants issued for services	-	-	-	-	350,000	-	-	-
Options exercised	25,000	-	-	-	15,000	-	-	-
Stock option compensation expense	-	-	-	-	415,000	-	-	-
Preferred stock issuances	-	-	272.5000	-	1,687,000	-	-	-
Warrants issued with preferred stock	-	-	-	-	1,142,000	-	-	-
Costs of stock issuances	-	-	-	-	(385,000)	-	-	-
Preferred stock dividend beneficial conversion feature	-	-	-	-	1,308,000	-	-	(1,308,000)
Common stock and warrants issued to Somanta shareholders	1,500,000	15,000	-	-	4,916,000	-	-	-
Common stock and warrants issued to Somanta creditors	538,000	5,000	-	-	1,571,000	-	-	-
Preferred stock converted into common stock	857,000	9,000	(257.0000)	-	(9,000)	-	-	-
Common stock issued for preferred dividends	452,000	5,000	-	-	427,000	-	-	-
Preferred dividends	-	-	-	-	-	-	-	(2,050,000)
Net loss	-	-	-	-	-	-	-	(17,215,000)
Balance, December 31, 2008	<u>6,967,000</u>	<u>\$ 70,000</u>	<u>3,242.8617</u>	<u>\$ -</u>	<u>\$127,482,000</u>	<u>\$ (1,045,000)</u>	<u>\$ (4,000)</u>	<u>\$ (134,897,000)</u>

The accompanying notes are an integral part of these consolidated statements.

**Access Pharmaceuticals, Inc. and Subsidiaries**

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (17,215,000)	\$ (21,744,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on extinguishment of debt	-	11,628,000
Stock option expense	415,000	1,048,000
Stock and warrants issued for services	377,000	83,000
Acquired in-process research & development	8,879,000	-
Depreciation and amortization	253,000	279,000
Amortization of debt costs and discounts	-	2,316,000
Loss on sale of assets	-	2,000
Change in operating assets and liabilities:		
Receivables	(747,000)	(607,000)
Prepaid expenses and other current assets	(80,000)	(127,000)
Other assets	(66,000)	14,000
Accounts payable and accrued expenses	176,000	310,000
Dividends payable	19,000	-
Accrued interest payable	(2,000)	1,150,000
Deferred revenue	1,431,000	805,000
Net cash used in operating activities	(6,560,000)	(4,843,000)
Cash flows from investing activities:		
Capital expenditures	(28,000)	(18,000)
Somanta acquisition, net of cash acquired	(65,000)	-
Proceeds from sale of asset	-	13,000
Net cash used in investing activities	(93,000)	(5,000)
Cash flows from financing activities:		
Payments of notes payable	(64,000)	(1,327,000)
Proceeds from preferred stock issuances, net of costs	2,444,000	8,672,000
Proceeds from exercise of stock options	15,000	35,000
Net cash provided by financing activities	2,395,000	7,380,000
Net increase (decrease) in cash and cash equivalents	(4,258,000)	2,532,000
Cash and cash equivalents at beginning of year	6,921,000	4,389,000
Cash and cash equivalents at end of year	\$ 2,663,000	\$ 6,921,000
<i>Supplemental cash flow information:</i>		
<i>Cash paid for interest</i>	\$ 435,000	\$ 34,000
<i>Supplemental disclosure of noncash transactions</i>		
<i>Shares issued for payables</i>	1,576,000	-
<i>Preferred stock dividends in dividends payable</i>	1,896,000	260,000
<i>Accrued interest capitalized</i>	-	511,000
<i>Warrants issued for placement agent fees</i>	104,000	523,000
<i>Beneficial conversion feature -</i>		
<i>February 2008 preferred stock dividends</i>	857,000	-
<i>November 2007 preferred stock dividends</i>	451,000	14,648,000
<i>Preferred stock issuance costs paid in cash</i>	281,000	345,000
<i>Debt exchanged for preferred stock</i>	-	10,015,000
<i>Accrued interest exchanges for preferred stock</i>	-	1,090,000
<i>Stock issued for preferred dividends</i>	432,000	-

The accompanying notes are an integral part of these consolidated statements.

**Access Pharmaceuticals, Inc. and Subsidiaries**

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
Two years ended December 31, 2008

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

Nature of Operations

Access Pharmaceuticals, Inc. is an emerging pharmaceutical company engaged in the development of novel therapeutics for the treatment of cancer and supportive care of cancer patients. This development work is based primarily on the adaptation of existing therapeutic agents using the Company's proprietary drug delivery technology. Our efforts have been principally devoted to research and development, resulting in significant losses since inception on February 24, 1988.

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

Principles of Consolidation

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

Reclassifications

Certain reclassifications to the Consolidated Financial Statements for all prior periods presented have been made to conform to the 2008 presentation.

Use of Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amount of assets and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reported period. Our significant estimates include primarily those required in the valuation of impairment analysis of intangible assets, property and equipment, revenue recognition, allowances for doubtful accounts, stock-based compensation and valuation of other equity instruments, valuation allowances for deferred tax assets and tax accruals. Although we believe that adequate accruals have been made for unsettled issues, additional gains or losses could occur in future years from resolutions of outstanding matters. Actual results could differ materially from original estimates.

Segments

The Company operates in a single segment.

Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2008 and 2007, we had no such investments. We maintain deposits primarily in one financial institution, which may at times exceed amounts covered by insurance provided by the U.S. Federal Deposit Insurance Corporation ("FDIC"). We have not experienced any losses related to amounts in excess of FDIC limits.

### Property and Equipment

Property and equipment are recorded at cost. Depreciation is provided using the straight-line method over estimated useful lives ranging from three to seven years. Expenditures for major renewals and betterments that extend the useful lives are capitalized. Expenditures for normal maintenance and repairs are expensed as incurred. The cost of assets sold or abandoned and the related accumulated depreciation are eliminated from the accounts and any gains or losses are recognized in the accompanying consolidated statements of operations of the respective period.

### Research and Development Expenses

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

### Fair Value of Financial Instruments

The carrying value of cash, cash equivalents, receivables, accounts payable and accruals approximate fair value due to the short maturity of these items. The carrying value of the convertible long-term debt is at book value which approximates the fair value as the interest rate is at market value.

### Income Taxes

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

As of January 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109, Accounting for Income Taxes* ("FIN 48"). The adoption did not have a material impact on our consolidated financial statements or effective tax rate and did not result in any unrecognized tax benefits. Interest costs and penalties related to income taxes are classified as interest expense and general and administrative costs, respectively, in our consolidated financial statements. For the years ended December 31, 2008 and 2007, we did not recognize any interest or penalty expense related to income taxes. It is determined not to be reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 12 months. We are currently subject to a three year statute of limitations by major tax jurisdictions. We and our subsidiaries file income tax returns in the U.S. federal jurisdiction.

### Loss Per Share

We have presented basic loss per share, computed on the basis of the weighted average number of common shares outstanding during the year, and diluted loss per share, computed on the basis of the weighted average number of common shares and all dilutive potential common shares outstanding during the year. Potential common shares result from stock options, vesting of restricted stock grants, convertible notes and warrants. However, for all years presented, all outstanding stock options, restricted stock grants, convertible notes and warrants are anti-dilutive due to the losses for the periods. Anti-dilutive common stock equivalents of 22,051,685 and 20,623,072 were excluded from the loss per share computation for 2008 and 2007, respectively.

## Patents

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

Intangible assets consist of the following (in thousands):

	<u>December 31, 2008</u>		<u>December 31, 2007</u>	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
Amortizable intangible assets - Patents	<u>\$ 1,680</u>	<u>\$ 1,138</u>	<u>\$ 1,680</u>	<u>\$ 970</u>

Amortization expense related to intangible assets totaled \$168,000 and \$193,000 for the years ended December 31, 2008 and 2007, respectively. The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2008 is as follows (in thousands):

2009	\$ 168
2010	168
2011	168
2012	<u>38</u>
Total	<u>\$ 542</u>

## Revenues

Our revenues are generated from licensing and research and development agreements. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104), *Revenue Recognition*. License revenue is recognized over the remaining life of the underlying patent. Research and development revenues are recognized as services are performed.

## Stock-Based Compensation

On January 1, 2006, we adopted SFAS No. 123 (revised 2004), "*Share-Based Payment*," ("SFAS 123(R)"), which requires the measurement and recognition of all share-based payment awards made to employees and directors including stock options based on estimated fair values. SFAS 123(R) supersedes the Company's previous accounting under Accounting Principles Board ("APB") Opinion No. 25, "*Accounting for Stock Issued to Employees*" ("APB 25"), for periods beginning in fiscal year 2006.

We used the Black-Scholes Option Pricing Model ("BSOPM") to determine the fair value of option grants made during 2008 and 2007. Commencing on January 1, 2007, we elected to use the "simplified" method per SEC Staff Accounting Bulletins No. 107 ("SAB 107"), "*Share Based Payment*," to calculate the estimated life of options granted to employees. The use of the "simplified" method under SAB 107 was extended beyond December 31, 2007 in accordance with Staff Accounting Bulletin 110 ("SAB 110"), "*Share Based Payment*," issued on December 21, 2007, until such time when we have sufficient information to make more refined estimates on the estimated life of our options. The expected stock price volatility was calculated by averaging the historical volatility of our common stock over a term equal to the expected life of the options.

SAB 110 expressed the views of the staff regarding the use of the “simplified” method, as discussed in SAB No. 107, in developing an estimate of expected term of “plain vanilla” share options in accordance with Statement of Financial Accounting Standards No. 123R, “Share-Based Payment”. SAB 110 allows public companies which do not have historically sufficient experience to provide a reasonable estimate to continue use of the “simplified” method for estimating the expected term of “plain vanilla” share options grants after December 31, 2007. We will continue to use the “simplified” method until we have enough historical experience to provide a reasonable estimate of expected term in accordance with SAB 110.

We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company’s 2006 fiscal year. Our consolidated financial statements for the years ended December 31, 2008 and 2007, reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our consolidated financial statements for prior periods have not been restated to include the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the year ended December 31, 2008 was approximately \$415,000 and \$1,048,000 for the year ended December 31, 2007.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service period. Prior to the adoption of SFAS 123(R), we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB No. 25 as allowed under SFAS No. 123, “Accounting for Stock-Based Compensation” (“SFAS 123”). Under the intrinsic value method, no stock-based compensation expense for stock option grants was recognized because the exercise price of our stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant.

We used the Black-Scholes option-pricing model (“Black-Scholes”) as our method of valuation under SFAS 123(R) in fiscal year 2008 and 2007 and a single option award approach. This fair value is then amortized on a straight-line basis over the requisite service periods of the awards, which is generally the vesting period. The fair value of share-based payment awards on the date of grant as determined by the Black-Scholes model is affected by our stock price as well as other assumptions. These assumptions include, but are not limited to the expected stock price volatility over the expected term of the awards, and actual and projected employee stock option exercise behaviors.

During 2008 and 2007, 305,000 stock options and 230,000 stock options, respectively, were granted under the 2005 Equity Incentive Plan. Assumptions for 2008 and 2007 are:

	2008	2007
Expected volatility assumption was based upon a combination of historical stock price volatility measured on a twice a month basis and is a reasonable indicator of expected volatility.	133%	136%
Risk-free interest rate assumption is based upon U.S. Treasury bond interest rates appropriate for the term of the Company’s employee stock options.	2.97%	4.65%
Dividend yield assumption is based on our history and expectation of dividend payments.	None	None
Estimated expected term (average of number years) is based on the simplified method as prescribed by SAB 107/110.	6.2 years	5.7 years

At December 31, 2008, the balance of unearned stock-based compensation to be expensed in future periods related to unvested share-based awards, as adjusted for expected forfeitures, is approximately \$665,000. The period over which the unearned stock-based compensation is expected to be recognized is approximately three years. We anticipate that we will grant additional share-based awards to employees in the future, which will increase our stock-based compensation expense by the additional unearned compensation resulting from these grants. The fair value of these grants is not included in the amount above, because the impact of these grants cannot be predicted at this time due to the dependence on the number of share-based payments granted. In addition, if factors change and different assumptions are used in the application of SFAS 123(R) in future periods, stock-based compensation expense recorded under SFAS 123(R) may differ significantly from what has been recorded in the current period.

Our Employee Stock Option Plans have been deemed compensatory in accordance with SFAS 123(R). Stock-based compensation relating to this plan was computed using the Black-Scholes model option-pricing formula with interest rates, volatility and dividend assumptions as of the respective grant dates of the purchase rights provided to employees under the plan. The weighted-average fair value of options existing under all plans during 2008 was \$3.12.

The following table summarizes stock-based compensation in accordance with SFAS 123(R) for the year ended December 31, 2008 and 2007 which was allocated as follows (in thousands):

	Year ended <u>December 31, 2008</u>	Year ended <u>December 31, 2007</u>
Research and development	\$ 108	\$ 91
General and administrative	<u>307</u>	<u>957</u>
Stock-based compensation expense included in operating expense	<u>415</u>	<u>1,048</u>
Total stock-based compensation expense	415	1,048
Tax benefit	-	-
Stock-based compensation expense, net of tax	<u>\$ 415</u>	<u>\$ 1,048</u>

#### Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standard (“SFAS”) No. 157, “Fair Value Measurements” (“SFAS 157”). SFAS 157 defines fair value, establishes a market-based framework or hierarchy for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is applicable whenever another accounting pronouncement requires or permits assets and liabilities to be measured at fair value. SFAS 157 does not expand or require any new fair value measures; however the application of this statement may change current practice. The requirements of SFAS 157 became effective for our fiscal year 2008. However, in February 2008 the FASB decided that an entity need not apply this standard to nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis until the subsequent year. Accordingly, our adoption of this standard on January 1, 2008 was limited to financial assets and liabilities and did not have a material effect on our financial condition or results of operations. We are still in the process of evaluating this standard with respect to its effect on nonfinancial assets and liabilities and therefore have not yet determined the impact that it will have on our financial statements upon full adoption.

In December 2007, the FASB issued SFAS No. 141 (revised 2007), “Business Combinations” (“SFAS 141(R)”) and SFAS No. 160, “Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51” (“SFAS 160”). SFAS 141(R) will significantly change current practices regarding business combinations. Among the more significant changes, SFAS 141(R) expands the definition of a business and a business combination; requires the acquirer to recognize the assets acquired, liabilities assumed and noncontrolling interests (including goodwill), measured at fair value at the acquisition date; requires acquisition-related expenses and restructuring costs to be recognized separately from the business combination; requires assets acquired and liabilities assumed from contractual and noncontractual contingencies to be recognized at their acquisition-date fair values with subsequent changes recognized in earnings; and requires in-process research and development to be capitalized at fair value as an indefinite-lived intangible asset. SFAS 160 will change the accounting and reporting for minority interests, reporting them as equity separate from the parent entity’s equity, as well as requiring expanded disclosures. SFAS 141(R) and SFAS 160 are effective for financial statements issued for fiscal years beginning after December 15, 2008. We are currently assessing the impact that SFAS 141(R) and SFAS 160 will have on our results of operations and financial position.

## NOTE 2 – LIQUIDITY

The accompanying consolidated financial statements have been prepared assuming that the Company is a going concern. The Company incurred a net loss in the years ended December 31, 2008 and 2007.

Management believes that our current cash and expected license fees should fund the Company's expected burn rate into the first quarter of 2010. The Company will require additional funds to fund operations. These funds are expected to come from the future sales of equity and/or license agreements.

## NOTE 3 - RELATED PARTY TRANSACTIONS

On February 12, 2008, the Board of Directors of the Company elected Steven H. Rouhandeh as director and Chairman of the Board effective as of March 4, 2008. Mr. Rouhandeh is Chief Investment Officer of SCO Capital Partners, L.P.

In the event SCO Capital Partners LLC ("SCO") and its affiliates were to convert all of their shares of Series A Preferred Stock and exercise all of their warrants, they would own approximately 59.0% of the voting securities of Access. During 2008 SCO and affiliates were paid \$191,000 in placement agent fees relating to the issuance of preferred stock and were issued warrants to purchase our 39,667 shares of our common stock. During 2007 SCO and affiliates were paid \$240,000 in placement agent fees relating to the issuance of preferred stock and were issued warrants to purchase our 100,000 shares of our common stock. SCO and affiliates also were paid \$232,000 in investor relations fees in 2008 and \$150,000 in investor relations fees in 2007.

On November 7, 2007, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 954,0001 shares of a newly created series of our preferred stock, designated "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series A Preferred Stock") and agreed to issue warrants to purchase 1,589,999 shares of our common stock at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Preferred Stock and Warrants of \$9,540,001. The shares of Series A Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share.

On November 7, 2007, as a condition to closing our sale of Series A Preferred Stock, SCO Capital Partners LLC and affiliates, along with the other holders of an aggregate of \$6,000,000 Secured Convertible Notes, also exchanged their notes and accrued interest for an additional 1,836.0512 shares of Series A Preferred Stock and were issued warrants to purchase 1,122,031 shares of our common stock at an exercise price of \$3.50 per share, and Oracle Partners LP and affiliates, along with the other holders of an aggregate of \$4,015,000 Convertible Notes also exchanged their notes and accrued interest for 437.3104 shares of the Series A Preferred Stock and were issued warrants to purchase 728,850 shares of our common stock at an exercise price of \$3.50 per share. In connection with the exchange of the notes, all security interests and liens relating thereto were terminated.

On November 7, 2007, as a condition to closing our sale of Series A Preferred Stock, we entered into an Investor Rights Agreement with each of the investors purchasing shares of Series A Preferred Stock and our Board of Directors approved with respect to the shareholder rights plan any action necessary under our shareholder rights plan to accommodate the issuance of the Series A Preferred Stock and warrants without triggering the applicability of the shareholder rights plan. In addition, we entered into an Investor Rights Agreement with the holders of Series A Preferred Stock. The Investor Rights Agreement grants certain registration and other rights to each of the investors.

In connection with the sale and issuance of Series A Preferred Stock and warrants, we entered into a Director Designation Agreement whereby we agreed to continue SCO's right to designate two individuals to serve on the Board of Directors of Access.

Lake End Capital LLC is known to beneficially own 335,575 shares of Access' Common Stock, warrants to purchase an aggregate of 777,026 shares of Access' Common Stock and Series A Preferred Stock which may be converted into an aggregate of 793,067 shares of Access' Common Stock. Jeffrey B. Davis, in his capacity as managing member of Lake End Capital LLC, has the power to direct the vote and disposition of the shares owned by Lake End Capital LLC. Mr. Davis is President of SCO Securities LLC, a wholly-owned subsidiary of SCO Financial Group LLC. Mr. Davis is also our CEO.

David P. Luci, one of our directors, participated in the February 2008 sale of our preferred stock. Mr. Luci purchased 2.5 preferred shares for \$25,000 and warrants to purchase 4,167 shares of our common stock. In addition, Mr. Luci was the President & Chief Business Officer of MacroChem, with which we acquired on February 25, 2009 pursuant to the Merger Agreement dated July 9, 2008.

Dr. Esteban Cvitkovic, a Director, has served as a consultant and Senior Director, Oncology Clinical Research & Development, since August 2007. Dr. Cvitkovic receives payments for consulting expenses, office expenses and reimbursement of direct expenses. Dr. Cvitkovic also has received the following warrants and options for his consulting. In January 2008, Dr. Cvitkovic received warrants to purchase 200,000 shares of our Common Stock at \$3.15 per share that can be exercised until January 4, 2012. The warrants vest over two years in 50,000 share blocks with vesting on July 4, 2008, January 4, 2009, July 4, 2009, and the remaining shares on January 4, 2010. In July 2007, Dr. Cvitkovic also received options to purchase 25,000 shares of our Common Stock at \$4.35 per share with all options currently vested. Dr. Cvitkovic's payments for consulting services and expense reimbursements are as follows:

Year	Consulting Fees	Office Expenses	Expense Reimbursement	Fair Value of exercisable Options/Warrants
2008	\$ 320,000	\$ 30,000	\$ 71,000	\$ 164,000
2007	\$ 153,000	\$ 15,000	\$ 12,000	\$ 76,000

Stephen B. Howell, M.D., a Director, received payments for consulting services and reimbursement of direct expenses. His consulting agreement expired in March 1, 2008. Dr. Howell's payments for consulting services and expense reimbursements are as follows:

Year	Consulting Fees	Expense Reimbursement
2008	\$ 31,000	\$ 3,000
2007	\$ 70,000	\$ 2,000

See Note 9 for a discussion of our Restricted Stock Purchase Program.

#### NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	December 31,	
	2008	2007
Laboratory equipment	\$ 831,000	\$ 824,000
Laboratory and building improvements	58,000	58,000
Furniture and equipment	75,000	40,000
	<u>964,000</u>	<u>922,000</u>
Less accumulated depreciation and amortization	877,000	792,000
Net property and equipment	<u>\$ 87,000</u>	<u>\$ 130,000</u>

Depreciation and amortization on property and equipment was \$85,000 and \$86,000 for the years ended December 31, 2008 and 2007, respectively.

## NOTE 5 – 401(k) PLAN

We have a tax-qualified employee savings and retirement plan (the “401(k) Plan”) covering all our employees. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit (\$15,500 in 2008 and 2007) and to have the amount of such reduction contributed to the 401(k) Plan. We have a 401(k) matching program whereby we contribute for each dollar a participant contributes a like amount, with a maximum contribution of 4% of a participant’s earnings in 2008 and 2007. The 401(k) Plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees or by us to the 401(k) Plan, and income earned on 401(k) Plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made. At the direction of each participant, we invest the assets of the 401(k) Plan in any of 62 investment options. Company contributions under the 401(k) Plan were approximately \$39,000 in 2008 and \$50,000 in 2007.

## NOTE 6 – DEBT

\$5,500,000 due on September 13, 2011. The unsecured convertible note bears interest at 7.7% per annum with \$423,500 of interest due annually on September 13<sup>th</sup>. During 2007, this investor amended this note’s due date until 2011 and delayed his interest payments which were due in 2005, 2006 and 2007 until September 13, 2008 or earlier if the Company raised more than \$5.0 million in funds. The capitalized interest was \$1,391,000 and interest on the capitalized interest was at 10%. We raised \$9,540,000 in November 2007, and entered into an agreement with the investor to pay capitalized interest of \$1,327,000 plus interest. At December 31, 2008, \$5,500,000 was due. At December 31, 2007 in addition to the note of \$5,500,000 an additional \$64,000 of capitalized interest was due. This note has a fixed conversion price of \$27.50 per share of common stock and may be converted by the note holder or us under certain circumstances as defined in the note. If the notes are not converted we will have to repay the notes on the due dates.

\$4,015,000 due on November 16, 2007 and \$6,000,000 due on November 15, 2007 exchanged for preferred stock.

On November 7, 2007, we entered into securities purchase agreements (the “Purchase Agreements”) with accredited investors whereby we agreed to sell 954,0001 shares of a newly created series of our preferred stock, designated “Series A Cumulative Convertible Preferred Stock”, par value \$0.01 per share, for an issue price of \$10,000 per share, (the “Series A Preferred Stock”) and agreed to issue warrants to purchase 1,589,999 shares of our common stock at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Preferred Stock and Warrants of \$9,540,000. The shares of Series A Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share.

As a condition to closing, SCO Capital Partners LLC and affiliates, along with the other holders of an aggregate of \$6,000,000 Secured Convertible Notes, also exchanged their notes and accrued interest for an additional 1,836.0512 shares of Series A Preferred Stock and were issued warrants to purchase 1,122,031 shares of our common stock at an exercise price of \$3.50 per share, and Oracle Partners LP and affiliates, along with the other holders of an aggregate of \$4,015,000 Convertible Notes also exchanged their notes and accrued interest for 437.3104 shares of the Series A Preferred Stock and were issued warrants to purchase 728,850 shares of our common stock at an exercise price of \$3.50 per share. SCO Capital Partners LLC currently has two designees serving on our Board of Directors. In connection with the exchange of the notes, all security interests and liens relating thereto were terminated.

The conversion of debt into equity resulted in a loss on extinguishment of debt of \$11,628,000 in 2007. This represents the difference between the fair value of the equity interest granted, based on recent sales of identical equity instruments, and the carrying amount of the debt and interest settled.

## NOTE 7 – COMMITMENTS AND CONTINGENCIES

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

<u>Future Maturities</u>	<u>Debt</u>
2011	5,500,000

### Operating Leases

At December 31, 2008, we have commitments under non-cancelable operating leases for office and research and development facilities until December 31, 2009 totaling \$77,000. Rent expense for the years ended December 31, 2008 and 2007 was \$107,000 and \$94,000, respectively. We also have one non-cancelable operating lease – for a copier with future obligations totaling \$29,000 ending in 2011 (with \$9,600 expensed each year).

### Legal

The Company is not currently subject to any material pending legal proceedings.

## NOTE 8 – PREFERRED STOCK

On February 4, 2008, we entered into securities purchase agreements (the “Purchase Agreements”) with accredited investors whereby we agreed to sell 272.50 shares of our preferred stock, designated “Series A Cumulative Convertible Preferred Stock”, par value \$0.01 per share, for an issue price of \$10,000 per share, (the “Series A Preferred Stock”) and agreed to issue warrants to purchase 454,167 shares of our common stock at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Preferred Stock and Warrants of \$2,725,000. Proceeds, net of cash issuance costs from the sale were \$2,444,000. The shares of Series A Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share.

In connection with the preferred stock offering, we issued warrants for placement agent fees to purchase a total of 45,417 shares of common stock. All of the warrants are exercisable immediately and expire six years from the date of issue. The fair value of the warrants was \$2.29 per share on the date of grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.75%, expected volatility 110% and an expected term of 6 years.

Emerging Issues Task Force (EITF) Issue 00-19, *Accounting for Derivative Financial Instruments Indexed to and Potentially Settled in, a Company's Own Stock*, to determine whether the instruments should be accounted for as equity or as liabilities.” EITF 00-19 requires the separation of single financial instruments into components. For example, common stock issued with warrants should be accounted for as equity, and the associated warrants could be classified as either equity or liability. We determined that the warrants issued along with the preferred stock and debt conversion are separate financial instruments and separately exercisable and, therefore, are within the scope of EITF 00-19. Both the preferred stock and warrants were classified as equity. The warrants were measured at their fair value.

The shares of Series A Preferred Stock are initially convertible into common stock at \$3.00 per share. Based on the price of our common stock on February 4, 2008 and the fair value attributed to the attached warrants, a new conversion price was calculated for accounting purposes. As a result of the change in conversion price for accounting purposes the preferred stock was considered to be “in the money”. This resulted in a beneficial conversion feature. The preferred stockholder has the right at any time to convert all or any lesser portion of the Series A Preferred Stock into common stock. This resulted in an intrinsic value of the preferred stock. The difference between the implied value of the preferred stock and the beneficial conversion option was treated as preferred stock dividends of \$857,000.

An additional \$451,000 in preferred stock dividends was recorded in the first quarter of 2008 as a result of a prior year correction. The change was due to preferred stock dividends and the beneficial conversion features associated with the warrants issued in connection with the November 2007 preferred stock agreement. The Company determined that the adjustment would have an immaterial effect to the Company's consolidated financial statements for the years ended December 31, 2008 and 2007, based on management's qualitative and quantitative analysis relative to its materiality consistent with the applicable accounting guidance.

Pursuant to the terms of an Investor Rights Agreement with the Purchasers of Series A Preferred Stock, the Company is required to maintain an effective registration statement. The Securities and Exchange Commission declared the registration statement effective November 13, 2008 relating to a portion of such securities, and as a result, the Company accrued \$675,000 in potential liquidated damages as of December 31, 2008. We may incur additional liquidated damages of 1% of the total Series A Preferred Stock proceeds for each 30 day period that the Registration Statement is not declared effective for all the shares. Potential liquidated damages are capped at 10% of the total subscription amount. However, pursuant to the terms of the Investor Rights Agreement, we may not be required to pay such liquidated damages if such shares are saleable without restriction pursuant to Rule 144 of the Securities Act of 1933.

Preferred stock dividends of \$1,896,000 were accrued through December 31, 2008, including interest. Dividends are required to be paid semi-annually in either cash or common stock.

On November 7, 2007, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 954,0001 shares of a newly created series of our preferred stock, designated "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series A Preferred Stock") and agreed to issue warrants to purchase 1,589,999 shares of our common stock at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Preferred Stock and Warrants of \$9,540,001. The shares of Series A Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share.

As a condition to closing, SCO Capital Partners LLC and affiliates, along with the other holders of an aggregate of \$6,000,000 Secured Convertible Notes, also exchanged their notes and accrued interest for an additional 1,836.0512 shares of Series A Preferred Stock and were issued warrants to purchase 1,122,031 shares of our common stock at an exercise price of \$3.50 per share, and Oracle Partners LP and affiliates, along with the other holders of an aggregate of \$4,015,000 Convertible Notes also exchanged their notes and accrued interest for 437.3104 shares of the Series A Preferred Stock and were issued warrants to purchase 728,850 shares of our common stock at an exercise price of \$3.50 per share. SCO Capital Partners LLC currently has two designees serving on our Board of Directors. In connection with the exchange of the notes, all security interests and liens relating thereto were terminated.

As a condition to closing, we entered into an Investor Rights Agreement with each of the investors purchasing shares of Series A Preferred Stock, and our Board of Directors approved with respect to the shareholder rights plan any action necessary under our shareholder rights plan to accommodate the issuance of the Series A Preferred Stock and warrants without triggering the applicability of the shareholder rights plan. Potential liquidated damages addressed in the Investor Rights Agreement are discussed above.

In connection with the sale and issuance of Series A Preferred Stock and warrants, we entered into a Director Designation Agreement whereby we agreed to continue SCO's right to designate two individuals to serve on the Board of Directors of Access.

The issued and outstanding shares of Series A Preferred Stock grants the holders of such preferred stock anti-dilution, dividend and liquidations rights that are superior to those held by the holders of our common stock. Should Access issue additional shares of common stock for a price below \$3.00 per share, the conversion price of the Series A Preferred Stock shall be lowered to the lowest issue price below \$3.00 per share which will have the effect of diluting the holders of our common stock.

In connection with the preferred stock offering, we issued warrants for placement agent fees, to purchase a total of 209,000 shares of common stock. All of the warrants are exercisable immediately and expire six years from date of issue. The fair value of the warrants was \$2.50 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.84%, expected volatility 114% and a term of 6 years.

The conversion of debt into equity resulted in a loss on extinguishment of debt of \$11,628,000. This represents the difference between the fair value of the equity interest granted, based on recent sales of identical equity instruments, and the carrying amount of the debt and interest settled.

Based on the loss on extinguishment of debt and the fair value allocated to the attached warrants for accounting purposes a new conversion price was calculated for the preferred stock and considered to be "in the money" at the time of the agreement to exchange the convertible notes for preferred stock. This resulted in a beneficial conversion feature. The preferred stockholder has the right at any time to convert all or any lesser portion of the Series A Preferred Stock into Common Stock. This resulted in an intrinsic value of the preferred stock. The difference between the implied value of the preferred stock and the beneficial conversion option was treated as preferred stock dividends of \$14,648,000.

## NOTE 9 – STOCKHOLDERS' EQUITY

### Restricted Stock Purchase Program

On October 12, 2000, the Board of Directors authorized a Restricted Stock Purchase Program. Under the Program, the Company's executive officers and corporate secretary were given the opportunity to purchase shares of common stock in an individually designated amount per participant determined by the Compensation Committee of the Board of Directors. A total of 38,000 shares were purchased under the Program by four eligible participants at \$27.50 per share, the fair market value of the common stock on October 12, 2000, for an aggregate consideration of \$1,045,000. The purchase price was paid through the participants' delivery of a 50%-recourse promissory note payable to the Company for three executive officer participants and a full-recourse promissory note payable to the Company for one participant. Each note bears interest at 5.87% compounded semi-annually and has a maximum term of ten years. The notes are secured by a pledge of the purchased shares to the Company. The Company recorded the notes receivable from participants in this Program of \$1,045,000 as a reduction of equity in the Consolidated Balance Sheet. Interest on the notes is neither being collected nor accrued. The stock granted under the Program is fully vested.

### Warrants

There were warrants to purchase a total of 9,687,326 shares of common stock outstanding at December 31, 2008. All warrants were exercisable at December 31, 2008, except for 175,000 warrants. The warrants had various prices and terms as follows:

<u>Summary of Warrants</u>	<u>Warrants Outstanding</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
2008 preferred stock offering (a)	499,584	\$ 3.5	2/24/14
2008 Somanta accounts payable (b)	246,753	3.5	1/04/14
2008 Warrants assumed on acquisition (c)	191,991	18.55-69.57	6/9/10-1/31/12
2008 investor relations advisor (d)	50,000	3.15	1/3/13
2008 investor relations advisor (e)	40,000	3	9/1/13
2008 scientific consultant (f)	200,000	3.15	1/4/12
2007 preferred stock offering (g)	3,649,880	3.5	11/10/13
2006 convertible note (h)	3,863,634	1.32	2/16/12
2006 convertible note (h)	386,364	1.32	10/24/12
2006 convertible note (h)	386,364	1.32	12/06/12
2006 investor relations advisor (i)	50,000	2.7	12/27/11
2004 offering (j)	89,461	35.5	2/24/09
2004 offering (j)	31,295	27	2/24/2009
2002 scientific consultant (k)	2,000	24.8	2/01/2009
Total	<u>9,687,326</u>		

- a) In connection with the preferred stock offering in February 2008, warrants to purchase a total of 499,584 shares of common stock were issued. All of the warrants are exercisable immediately and expire six years from date of issue. The fair value of the warrants was \$2.29 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.75%, expected volatility 110% and a term of 6 years.
- b) In exchange for \$1,576,000 due Somanta vendors, the vendors were given 538,508 shares of common stock and warrants to purchase 246,753 shares of common stock at \$3.50. The warrants expire January 4, 2014.
- c) We assumed three warrants in the Somanta acquisition:
- Warrant #1 - 323 shares of our common stock at \$69.57 per share and expires June 9, 2010.
  - Warrant #2 - 31,943 shares of our common stock at \$18.55 per share and expires January 31, 2012.
  - Warrant #3 - 159,725 shares of our common stock at \$23.19 per share and expires January 31, 2012.
- d) During 2008, an investor relations advisor received warrants to purchase 50,000 shares of common stock at an exercise price of \$3.15 per share at any time until January 3, 2013, for investor relations consulting services to be rendered in 2008. 25,000 of the warrants were exercisable on July 3, 2008 and 25,000 of the warrants will be exercisable January 3, 2009. The fair value of the warrants was \$2.24 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.13%, expected volatility 127% and a term of 5 years.
- e) During 2008, an investor relations advisor received warrants to purchase 40,000 shares of common stock at an exercise price of \$3.00 per share at any time until September 1, 2013, for investor relations consulting services. All of the warrants are exercisable. The fair value of the warrants was \$2.61 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.37%, expected volatility 132% and a term of 5 years.
- f) During 2008, a director who is also a scientific advisor received warrants to purchase 200,000 shares of common stock at an exercise price of \$3.15 per share at any time until January 4, 2012, for scientific consulting services rendered in 2008. The warrants vest over two years in 50,000 share blocks with vesting on July 4, 2008, January 4, 2009, July 4, 2009 and the remaining shares on January 4, 2010. The fair value of the warrants was \$1.78 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.01%, expected volatility 92% and a term of 4 years.
- g) In connection with the preferred stock offering in November 2007, warrants to purchase a total of 3,649,880 shares of common stock were issued. All of the warrants are exercisable immediately and expire six years from date of issue. The fair value of the warrants was \$2.50 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.84%, expected volatility 114% and a term of 6 years.

- h) In connection with the convertible note offerings in 2006, warrants to purchase a total of 4,636,362 shares of common stock were issued. All of the warrants are exercisable immediately and expire six years from date of issue.
- i) During 2006, an investor relations advisor received warrants to purchase 50,000 shares of common stock at an exercise price of \$2.70 per share at any time from December 27, 2006 until December 27, 2011, for investor relations consulting services rendered in 2007. All of the warrants are exercisable.
- j) In connection with offering of common stock in 2004, warrants to purchase a total of 120,756 shares of common stock were issued. All of the warrants are exercisable and expire five years from date of issuance.
- k) During 2002, a director who is also a scientific advisor received warrants to purchase 2,000 shares of common stock at an exercise price of \$24.55 per share at any time until February 1, 2009, for scientific consulting services rendered in 2002.

#### 2001 Restricted Stock Plan

We have a restricted stock plan, the 2001 Restricted Stock Plan, as amended, under which 80,000 shares of our authorized but unissued common stock were reserved for issuance to certain employees, directors, consultants and advisors. The restricted stock granted under the plan generally vests, 25% two years after the grant date with additional 25% vesting every anniversary date. All stock is vested after five years. At December 31, 2008 there were 27,182 shares issued and 52,818 shares available for grant under the 2001 Restricted Stock Plan. All the issued shares are vested.

#### **NOTE 10 - STOCK OPTION PLANS**

We have various stock-based employee compensation plans described below:

#### 2005 Equity Incentive Plan

We have a stock awards plan, (the "2005 Equity Incentive Plan"), under which 3,150,000 shares of our authorized but unissued common stock were reserved for issuance to employees of, or consultants to, one or more of the Company and its affiliates, or to non-employee members of the Board or of any board of directors (or similar governing authority) of any affiliate of the Company. The 2005 Equity Incentive Plan replaced the previously approved stock option plan (the 1995 Stock Awards Plan").

For the 2005 Equity Incentive Plan, the fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in fiscal 2008: dividend yield of 0%; volatility of 133%; risk-free interest rate of 2.97%; and expected lives of 6.2 years. The weighted average fair value of options granted was \$2.73 per share during 2008. The assumptions for grants in fiscal 2007 were: dividend yield of 0%; volatility of 136%; risk-free interest rate of 4.65%; and expected lives of 5.7 years. The weighted average fair value of options granted was \$3.27 per share during 2007.

Summarized information for the 2005 Equity Incentive Plan is as follows:

	Options	Weighted- average exercise price
Outstanding options at January 1, 2007	802,672	\$ 1.04
Granted, fair value of \$ 3.27 per share	230,000	3.62
Exercised	(31,286)	1.11
Expired	(75,000)	2.14
Outstanding options at December 31, 2007	<u>926,386</u>	1.59
Granted, fair value of \$ 2.73 per share	305,000	3.00
Exercised	(25,250)	0.63
Expired	(69,316)	3.17
Outstanding options at December 31, 2008	<u><u>1,136,820</u></u>	1.90
Exercisable at December 31, 2008	859,112	1.53

The intrinsic value of options under this plan related to the outstanding and exercisable options were \$229,000 at December 31, 2008. The intrinsic value of options under this plan related to the outstanding and exercisable options were \$1,805,000 and \$1,504,000, respectively, at December 31, 2007.

The total intrinsic value of options exercised during 2008 was \$60,000 and during 2007 was \$113,000.

Further information regarding options outstanding under the 2005 Equity Incentive Plan at December 31, 2008 is summarized below:

Range of exercise prices	Number of options outstanding	Weighted average		Number of options exercisable	Weighted-average	
		Remaining life in years	Exercise price		Remaining life in years	Exercise price
\$0.63 - 0.85	641,500	8.0	\$0.63	641,500	8.0	\$0.63
\$2.90 - 7.23	<u>495,320</u>	9.2	\$3.53	<u>217,612</u>	8.5	4.16
	<u><u>1,136,820</u></u>			<u><u>859,112</u></u>		

#### 2007 Special Stock Option Plan

In January 2007 we adopted the 2007 Special Stock Option Plan and Agreement (the "Plan"). The Plan provides for the award of options to purchase 450,000 shares of the authorized but unissued shares of common stock of the Company. At December 31, 2008, there were 350,000 additional shares available for grant under the Plan.

Under the 2007 Special Stock Option Plan, 450,000 options were issued in 2007 and 350,000 were forfeited. 100,000 options were outstanding at December 31, 2008 and 2007. 100,000 options in the 2007 Special Stock Option Plan were exercisable at December 31, 2008 and 2007. All of the options had an exercise price of \$2.90 per share and expire March 12, 2010.

For the 2007 Special Stock Option Plan, the fair value of options was estimated at the date of grant using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in fiscal 2007: dividend yield of 0%; volatility of 138%; risk-free interest rate of 4.66%; and expected lives of 5.0 years. The weighted average fair value of options granted was \$2.70 per share during 2007.

#### 1995 Stock Awards Plan

Under the 1995 Stock Awards Plan, as amended, 500,000 shares of our authorized but unissued common stock were reserved for issuance to optionees including officers, employees, and other individuals performing services for us. At December 31, 2008, there were no additional shares available for grant under the 1995 Stock Awards Plan. A total of 118,000 options were outstanding under this plan at December 31, 2008.

Options granted under all the plans generally vest ratably over a four to five year period and are generally exercisable over a ten-year period from the date of grant. Stock options were generally granted with an exercise price equal to the market value at the date of grant.

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

	Options	Weighted- average exercise price
Outstanding options at January 1, 2007	360,917	\$ 18.03
Expired	(198,500)	20.07
Outstanding options at December 31, 2007	162,417	15.53
Expired	(44,417)	16.57
Outstanding options at December 31, 2008	118,000	15.14
Exercisable at December 31, 2008	116,558	15.18

There was no intrinsic value related to outstanding or exercisable options under this plan at December 31, 2008 or 2007.

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2008 is summarized below:

Range of exercise prices	Number of Options outstanding	Weighted average		Number of options exercisable	Weighted-average	
		Remaining life in years	Exercise price		Remaining life in years	Exercise price
\$10.00 - 12.50	75,640	4.2	\$11.39	74,198	4.1	\$11.39
\$14.05 - 18.65	22,800	3.9	\$17.76	22,800	3.9	\$17.76
\$20.25 - 29.25	19,560	5.3	\$26.58	19,560	5.3	\$26.58
	118,000			116,558		

Two directors, who retired from our board of directors May 21, 2008, were granted two years until May 21, 2010 to exercise their vested stock options. This modification resulted in \$100,000 in stock option expense that was recognized in year ending December 31, 2008.

#### NOTE 11 - SOMANTA ACQUISITION

On January 4, 2008, we acquired all the outstanding shares of Somanta Pharmaceuticals, Inc (“Somanta”). Somanta was engaged in the pharmaceutical development business. We anticipate that the acquisition will add additional product pipelines and complement our existing product pipelines. Total consideration paid in connection with the acquisition included:

- Approximately 1.5 million shares of Access common stock were issued to the common and preferred shareholders of Somanta as consideration having a value of approximately \$4,650,000 (the value was calculated using Access’ stock price on January 4, 2008, times the number of shares issued);
- exchange of all outstanding warrants for Somanta common stock for warrants to purchase 191,991 shares of Access common stock at exercise prices ranging between \$18.55 and \$69.57 per share. The warrants were valued at approximately \$281,000. All of the warrants are exercisable immediately and expire approximately four years from date of issue. The weighted average fair value of the warrants was \$1.46 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.26%, expected volatility 114% and an expected term of approximately 4 years;
- paid an aggregate of \$475,000 in direct transaction costs; and
- cancelled receivable from Somanta of \$931,000.

The following table summarizes the initial fair values of the assets acquired and liabilities assumed at the date of the acquisition (in thousands) based on a preliminary valuation. Subsequent adjustments may be recorded upon the completion of the valuation and the final determination of the purchase price allocation.

Cash	\$	1
Prepaid expenses		25
Office equipment		14
Accounts payable		(2,582)
In-process research & development		8,879
	<u>\$</u>	<u>6,337</u>

Approximately \$8,879,000 of the purchase price represents the estimated fair value of the acquired in-process research and development projects that have no alternative future use. Accordingly this amount was immediately expensed as research and development in the consolidated statement of operations upon the acquisition date.

Operating results of Somanta have been included in our consolidated financial statements since January 4, 2008.

The following unaudited pro forma information presents the 2008 and 2007 results of the Company as if the acquisition had occurred on January 1, 2007. The unaudited pro forma results are not necessarily indicative of results that would have occurred had the acquisition been in effect for the periods presented, nor are they necessarily indicative of future results. Net loss for Somanta for the 2007 period is for nine months ended October 31, 2007, based on its fiscal year. No significant operations occurred after October 31, 2008 until the acquisition on January 4, 2008. Amounts are shown in thousands.

	<b>Twelve months ended</b>	
	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Net loss allocable to common stockholders	\$ (20,573)	\$ (33,902)
Net loss per common shares (basic and diluted)	\$ (3.51)	\$ (6.71)
Weighted average common shares outstanding (basic and diluted)	5,854	5,052

#### **NOTE 12 - INCOME TAXES**

Income tax expense differs from the statutory amounts as follows:

	<u>2008</u>	<u>2007</u>
Income taxes at U.S. statutory rate	(\$6,995,000)	(\$7,393,000)
Change in valuation allowance	2,155,000	3,015,000
Change in miscellaneous items	-	-
Benefit of foreign losses not recognized	59,000	56,000
Expenses not deductible	4,224,000	3,957,000
Expiration of net operating loss and general business credit carryforwards, net of revisions	<u>557,000</u>	<u>365,000</u>
<b>Total tax expense</b>	<u>\$ -</u>	<u>\$ -</u>

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

	<u>December 31,</u>	
	<u>2008</u>	<u>2007</u>
Deferred tax assets		
Net operating loss carryforwards	\$ 26,289,000	\$ 25,693,000
General business credit carryforwards	3,217,000	2,469,000
Property, equipment and goodwill	54,000	87,000
Deferred revenue	310,000	-
Other	<u>534,000</u>	<u>-</u>
Gross deferred tax assets	30,404,000	28,249,000
Valuation allowance	<u>(30,404,000)</u>	<u>(28,249,000)</u>
Net deferred taxes	<u>\$ -</u>	<u>\$ -</u>

At December 31, 2008, we had approximately \$77,320,000 of net operating loss carryforwards and approximately \$3,217,000 of general business credit carryforwards. These carryforwards expire as follows:

	<u>Net operating loss carryforwards</u>	<u>General business credit carryforwards</u>
2009	\$ 1,661,000	\$ 193,000
2010	2,171,000	157,000
2012	4,488,000	30,000
2013	4,212,000	94,000
2014	3,324,000	129,000
Thereafter	<u>61,464,000</u>	<u>2,614,000</u>
	<u>77,320,000</u>	<u>3,217,000</u>

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

As of January 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109, Accounting for Income Taxes* ("FIN 48"). The adoption did not have a material impact on our consolidated financial statements or effective tax rate and did not result in any unrecognized tax benefits. Interest costs and penalties related to income taxes are classified as interest expense and general and administrative costs, respectively, in our consolidated financial statements. For the years ended December 31, 2008 and 2007, we did not recognize any interest or penalty expense related to income taxes. It is determined not to be reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 12 months. We are currently subject to a three year statute of limitations by major tax jurisdictions. We and our subsidiaries file income tax returns in the U.S. federal jurisdiction.

**NOTE 13 – QUARTERLY FINANCIAL DATA (UNAUDITED)**

Our results of operations by quarter for the years ended December 31, 2008 and 2007 were as follows (in thousands, except per share amounts):

	2008 Quarter Ended			
	March 31	June 30	September 30	December 31
Loss from continuing operations	\$ (10,595)	\$ (2,243)	\$ (2,806)	\$ (1,571)
Preferred stock dividends	(1,833)	(517)	(523)	(485)
Net loss allocable to common Stockholder	<u>\$ (12,428)</u>	<u>\$ (2,760)</u>	<u>\$ (3,329)</u>	<u>\$ (2,056)</u>
Basic and diluted loss per common share	<u>\$ (2.31)</u>	<u>\$ (0.49)</u>	<u>\$ (0.57)</u>	<u>\$ (0.31)</u>

	2007 Quarter Ended			
	March 31	June 30	September 30	December 31
Loss from continuing operations	\$ (4,127)	\$ (2,109)	\$ (1,957)	\$ (13,663)
Preferred stock dividends	-	-	-	(14,908)
Discontinued operations, net of tax	-	-	-	112
Net loss allocable to common Stockholder	<u>\$ (4,127)</u>	<u>\$ (2,109)</u>	<u>\$ (1,957)</u>	<u>\$ (28,459)</u>
Basic and diluted loss per common share	<u>\$ (1.17)</u>	<u>\$ (0.60)</u>	<u>\$ (0.55)</u>	<u>\$ (8.00)</u>

**NOTE 14 – SUBSEQUENT EVENTS (UNAUDITED)**

On February 25, 2009 we closed the acquisition of MacroChem Corporation. In connection with the merger, Access issued an aggregate of approximately 2.5 million shares of Access Pharmaceuticals, Inc. common stock to the holders of MacroChem common stock and in-the-money warrant holders as consideration, having a value of approximately \$3,500,000 (the value was calculated using Access' stock price on February 25, 2009, times the number of shares issued). We anticipate that the acquisition will add additional product pipelines and complement our existing product pipelines. The purchase price allocation has not been completed as of the filing date of this Form 10-K.

In addition, on February 25, 2009, we issued 859,172 shares of our unregistered common stock to the holders of \$825,000 of MacroChem notes and interest in exchange for cancellation of those notes. Additionally, on February 25, 2009 we issued 95,000 shares of our unregistered common stock in exchange for the cancellation of employment agreements to three former executives of MacroChem. The securities issued to the former MacroChem noteholders and the former executives were issued under section 4(2) of the Securities Act, as amended.



**Subsidiaries of the Registrant**

Access Pharmaceuticals Australia Pty. Limited, a New South Wales, Australia company

MacroChem Corporation, a Delaware company

Somanta Pharmaceuticals, Inc., a Delaware company

Tacora Corporation, a Delaware company

Virologix Corporation, a Delaware company

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have issued our report dated March 31, 2009, accompanying the consolidated financial statements included in the Annual Report of Access Pharmaceuticals, Inc. on Form 10-K for the year ended December 31, 2008. We hereby consent to the incorporation by reference of said report in the Registration Statements of Access Pharmaceuticals, Inc. on Form S-1 (File Nos. 333-149633, 333-125349, and 333-135734), Form S-3 (File Nos. 333-92210, 333-39330, 333-37786, 333-52030, 333-95413, 333-64904, and 333-113909), Form S-4 (File Nos. 333-155885 and 333-143587), and Form S-8 (File Nos. 333-45646, 333-75136, 333-125796, and 333-114269).

/s/ WHITLEY PENN LLP

Dallas, Texas  
March 31, 2009

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CHIEF EXECUTIVE OFFICER CERTIFICATION PURSUANT TO 18 U.S.C.  
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302  
OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey B. Davis, certify that:

1. I have reviewed this report on Form 10-K of Access Pharmaceuticals, Inc.
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officer(s) 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 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 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 report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this 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; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - 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.

Dated: March 31, 2009

/s/ Jeffrey B. Davis  
Jeffrey B. Davis  
Chief Executive Officer



CHIEF FINANCIAL OFFICER CERTIFICATION PURSUANT TO 18 U.S.C.  
SECTION 1350, AS ADOPTED PURSUANT TO SECTION 302  
OF THE SARBANES-OXLEY ACT OF 2002

I, Stephen B. Thompson, certify that:

1. I have reviewed this report on Form 10-K of Access Pharmaceuticals, Inc.
2. Based on my knowledge, this 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 report;
3. Based on my knowledge, the financial statements, and other financial information included in this 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 report;
4. The registrant's other certifying officer(s) 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 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 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 report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this 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; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - 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.

Dated: March 31, 2009

/s/ Stephen B. Thompson  
Stephen B. Thompson  
Chief Financial Officer



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

This certification set forth below is hereby made solely for the purposes 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.

A signed original of this written statement required by Section 906 has been provided to Access Pharmaceuticals, Inc. and will be retained by Access Pharmaceuticals, Inc. and furnished to the SEC or its staff upon its request.

Pursuant to Section 906 of the Public Company Accounting Reform and Investor Act of 2002 (18 U.S.C. 1350, as adopted, the "Sarbanes-Oxley Act"), Jeffrey B. Davis, Chief Executive Officer of Access Pharmaceuticals, Inc. (the "Company"), and Stephen B. Thompson, Vice President and Chief Financial Officer of the Company, each hereby certifies that to his knowledge the Annual Report on Form 10-KSB for the period ended December 31, 2008 of the Company filed with the Securities and Exchange Commission on the date hereof (the "Report") fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period specified.

Signed at the City of Dallas, in the State of Texas, this 31st day of March, 2009.

/s/ Jeffrey B. Davis  
Jeffrey B. Davis  
Chief Executive Officer

/s/ Stephen B. Thompson  
Stephen B. Thompson  
Chief Financial Officer