

**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, 2012

or

**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 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

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$0.01 par value

**Title of each Class**

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) 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 Act. (Check one):

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Large accelerated filer       Accelerated filer       Non-accelerated filer       Smaller reporting company   
(Do not check if a 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 o No x

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, 2012, was approximately \$15,637,000.

The number of shares outstanding of the registrant's common stock as of March 19, 2013 was 24,732,312 shares. Also outstanding at March 19, 2013 were 2,913.3617 shares of Series A Cumulative Convertible Preferred Stock convertible into 58,267,234 shares of common stock and 1,000.0 shares of Series B Cumulative Convertible Preferred Stock convertible into 20,000,000 shares of common stock

**DOCUMENTS INCORPORATED BY REFERENCE.**

Portions of the registrant's definitive Proxy Statement relating to our 2013 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 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 and, except as required by law, we do not intend to update any forward-looking statements even if new information becomes available or other events occur in the future.

#### **Business**

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 and, except as required by law, we do not intend to update any forward-looking statements even if new information becomes available or other events occur in the future.

#### **Marketed Product**

- MuGard™ is our marketed 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 \$2.1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the FDA. We launched MuGard in the United States in the fourth quarter of 2010. We are continuing the training of our third-party MuGard representatives on the product, on the oral mucositis condition and on our sales strategy. MuGard prescriptions are growing quarterly and we have placed emphasis on our sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake. MuGard was launched in certain European countries by SpePharm Holding, B.V. (“SpePharm”). By mutual agreement, the partner agreement with SpePharm was terminated in 2012. We are actively seeking a new European commercial partner for MuGard. Our China partners have received an acceptance letter from the State Food and Drug Administration of the People’s Republic of China which provides marketing approval in China. MuGard has been manufactured in the U.S. and shipped to China for sale. Our China partners anticipate sales of MuGard will begin in China in the second quarter of 2013.

**Product Candidates**

- Our candidate for the treatment of cancer is ProLindac™, a nanopolymer Diamino Cyclohexane (“DACH”)-platinum prodrug. We have completed and evaluated data from several clinical trials with ProLindac. No additional trials have been initiated this year in the US and in Europe as the company is focusing its resources on growing sales of MuGard. We are working with our partner in China towards the initiation of clinical trials of ProLindac in China. Clinical studies of other indications including liver, colorectal and ovarian cancer are under consideration by Jiangsu Aosaikang Pharmaceutical Co., Ltd, our licensee for ProLindac in China. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has had annual sales in excess of \$2.0 billion.
- CobOral® is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We have been developing a product for the oral delivery of insulin, and have conducted sponsored development of a product for oral delivery of a number of peptides and RNAi therapeutics. We are currently seeking partners to license this technology.\
- CobaCyte®-mediated 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 certain cells including many cancers. This technology uses nanopolymer constructs to deliver more anti-cancer drug to tumors while protecting normal tissues. We are currently seeking partners to license this technology.

Thiarabine, or 4-thio Ara-C, a next generation nucleoside analog which was 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 were working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and had initiated additional Phase 2 clinical trials in adult AML, ALL and other indications. In the third quarter of 2012 we terminated our license with Southern Research Institute, terminated the trial and are no longer proceeding with this product.

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	Launched U.S. and EU Regulatory Approval China
ProLindac™ (Polymer Platinate, AP5346) (2)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Oral Insulin	Access	Cobalamin	Diabetes	Pre-clinical
CobOral® Delivery System	Access	Cobalamin	Various	Pre-clinical
CobaCyte®-Targeted Therapeutics	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.

**Approved Product**

MuGard™

Overview of MuGard

Mucositis is a debilitating condition involving extensive ulceration of the oral cavity that affects annually an estimated 400,000 cancer patients in the United States undergoing chemotherapy and radiation treatment. We believe that 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 \$2.1 billion world-wide.

Our MuGard is a viscous hydrogel 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 of mucositis. On December 13, 2006, we announced our receipt of marketing clearance for MuGard from the 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 under which SpePharm was to market MuGard in Europe. MuGard sales started in Europe in the second quarter of 2009. The agreement with SpePharm was terminated in 2012 and we are actively seeking a new European commercial partner for MuGard sales. In January 2008, we signed a definitive licensing agreement with RHEI Pharmaceuticals, Inc. (“RHEI”), which was later sub-licensed to Jian An Pharmaceutical Ltd (“Jian An”), under which Jian An markets MuGard in China and other Southeast Asian countries.

On July 29, 2009, we took control of the North American rights to MuGard from a previous partner which had not received required funding to launch the product in the U.S. In addition, we announced that we are evaluating strategic options for the commercialization of MuGard in North America. Mr. Frank Jacobucci joined Access, as Vice President, Sales and Marketing, to assist with ongoing reimbursement, manufacturing and commercial launch activities, while discussions with potential licensee and co-promotion partners are ongoing. Also, in 2011, Mr. Anthony Mattola joined Access, as Vice President, Managed Care and Market Access, to assist with managed care, and ongoing reimbursement activities.

On September 11, 2009, we announced the appointment of Accupac, Inc. as our U.S. manufacturer for MuGard.

#### Current Status of MuGard

We launched MuGard in the U.S. in the fourth quarter of 2010. MuGard had been launched in Germany, Italy, UK, Greece and the Nordic countries by our former European commercial partner, SpePharm. Our partners in China have received registration and marketing approvals.

Access initiated a new clinical study of the safety and effectiveness of MuGard in the first quarter of 2011. Accrual into this study is ongoing. The study is a controlled, randomized, double-blinded trial of MuGard with a standard treatment for mucositis as a comparator in patients receiving chemoradiation for head and neck cancer. Interim results were announced in mid-2012 indicating that patients on MuGard had lower scores of mouth and throat soreness than those in the control group, in spite of the fact that more patients in the control group used opiate analgesics and control group patients used opiates longer than those in the MuGard group. Patients in the MuGard group had less weight loss than those in the control group indicating that patients in the MuGard group had a superior nutritional status. Several parameters comparing patients in the MuGard group to those in the control group already showed a statistically significant difference. In all these cases, the average scores for MuGard were superior to those for patients in the control group. The study is continuing to enroll patients to increase the total patient population.

We are currently executing on numerous strategies including the implementation of a dedicated sales force and marketing strategies, sampling programs, reimbursement strategies, the clinical advancement program for MuGard involving some of the foremost thought leaders in the oral mucositis arena as well as the advancement of the other uniquely differentiated products within our pipeline.



## Products in Development

### ProLindac™ (Polymer Platinate, 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 their 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. Clinicians will often use a combination of chemotherapeutic drugs, a dosing schedule and a method of administration designed 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 2008. 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 leucovorin (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 worldwide sales in excess of \$2.0 billion in 2010. 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 (hydroxypropylmerthacrylamide or "HPMA") as a drug carrier, our drug candidate ProLindac, links DACH platinum to a polymer in a manner which permits the selective release of the 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 melanoma 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.

We have completed and evaluated data from several clinical trials with ProLindac. No additional trials have been initiated this year in the US and in Europe as the company is focusing its resources on growing sales of MuGard. We are working with our partner in China towards the initiation of clinical trials of ProLindac in China.

## **Drug Development Strategy**

We have a rich potential pipeline of products and product candidates ranging from preclinical development candidates to one approved product. To maximize return on this portfolio, we plan to develop in-house and with collaborators the following products and technologies: MuGard, ProLindac, and CobaCyte/CobOral.

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. We do not spend significant resources on fundamental biological research but rather focus on our 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 CobOral-mediated oral drug delivery and CobaCyte-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 ProLindac. To reduce financial risk and financing requirements, we are directing our resources to the preclinical and early clinical phases of development. We plan to co-develop with or to outlicense to marketing partners our therapeutic product candidates where the size of the necessary clinical studies and cost associated with the later clinical development phases are significant. 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 plan to contract certain research and development, manufacturing and manufacturing scaleup, 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 also plan to 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 generally 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 to obtain regulatory approval to conduct clinical trials. 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 advanced phases of this process conducted by a development partner. We expect to engage a contract research organization to perform Phase 3 clinical studies to the extent they are conducted.

We contract with third party contract research organizations 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. Our licensees are funding these trials.

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 \$2,010,000 and \$3,579,000 on research and development during the years 2012 and 2011, respectively.

## **Scientific Background**

We possess a broad range of technologies and intellectual property in the areas of drug delivery and oncology. Our core technologies rely on the use of nanopolymers for use in the management of oral conditions such as mucositis, and in drug delivery. In addition, we have small molecule, peptide, protein, and oligonucleotide programs which also embody the principals of drug delivery and drug targeting.

In our drug delivery programs for oncology, we believe 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 oncology 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 and extending tumor exposure to drug. 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 delivery system, 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.

Our CobOral drug delivery technology seeks to deliver drugs orally to systemic circulation and CobaCyte to diseased cells. The main use of the CobOral technology will be to deliver drugs orally that otherwise could only be administered by injection because of poor natural oral absorption and/or degradation in the gastrointestinal tract. While other oral drug delivery technologies have been reported, the majority rely on permeation enhancement. Permeation enhancement temporarily increase the gaps between the cells which line the gastrointestinal tract to allow more drug to pass through. But this technique also allows many other materials, many potentially toxic, to enter the body more readily. Additionally, permeation enhancers only permit a small increase in oral uptake. The CobOral technology relies upon a natural receptor-mediated uptake mechanism which can facilitate uptake of larger quantities of drug. Our nanopolymer technology is used to encapsulate the drug, protecting it in the harsh environment of the gastrointestinal tract, and permits slow drug release once transported into systemic circulation.

## **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;
- CobOral®-Mediated Oral Delivery Technology; and
- CobaCyte®-Mediated Targeted Delivery Technology.

Each of these platforms is discussed below:

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

Our technology originally came from a collaboration with The School of Pharmacy, University of London, and we developed a synthetic polymer technology, which utilizes a HEMA polymer with platinum, designed to exploit enhanced permeability and retention effect, 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. The increased tumor uptake of macromolecules and decreased clearance are the main elements of EPR, and is thought to constitute the mechanism of action of styrene-maleic/anhydride-neocarzinostatin, or SMANCS, a polymer therapeutic 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.

### **CobOral®-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 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 naturally-produced intrinsic factor (IF) in the small intestine, and the VB12-IF complex then binds to the IF receptor on the surface of the intestine. Receptor-mediated endocytosis then allows the transport of VB12 across the gut wall. After binding to another VB12-binding protein, transcobalamin II (TcII), VB12 is transferred to the bloodstream.

Our scientists discovered that VB12 will still be transported by this process even when drugs, macromolecules, or nanoparticles are coupled to the VB12. Thus CobOral (VB12 conjugates of drugs, macromolecules, or nanoparticles) 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 CobOral. If the capacity of the CobOral 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 CobOral 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 CobOral. 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 CobOral or its analogs to a polymer to which the drug to be delivered is also attached, or 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, oral uptake 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.

### **CobaCyte®-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 following delivery to the bloodstream 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 CobaCyte-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 ProLindac program uses 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 binding 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 CobaCyte compounds (analogs of vitamin B12), but we have also used and have certain intellectual property protection for the use of folate and biotin in combination with vitamin B12 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 hemotopoietic cells and methotrexate-sensitive tumors.

#### Current Status of CobOral and CobaCyte

Access has ongoing collaborations with several companies to examine the application of Access' vitamin B12 drug delivery technologies for oral and targeted delivery of actives. These collaborations are focused on improved peptide delivery in the treatment of diabetes and cancer, and in the delivery of RNAi therapeutics to specific target genes.



In a collaboration with a leading RNAi therapeutics company, promising preliminary data were obtained by our collaborator showing that the CobaCyte delivery technology enhanced oligonucleotide delivery to target cells in vitro. Discussions are ongoing to conduct additional studies aimed at providing additional proof-of-concept data supporting the potential of CobaCyte targeting of RNAi therapies.

### **Other Key Developments**

On November 2, 2012 we paid our secured noteholder \$2,750,000 plus accrued interest. The note and the security agreement are terminated and no further amounts are owed under the note or the security agreement.

On October 25, 2012, we entered into a Preferred Stock and Warrant Purchase Agreement (the "Purchase Agreement") with existing investors whereby we agreed to sell 1,000 shares of a newly created series of our preferred stock, designated "Series B Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series B Preferred Stock") and issued warrants to purchase 20,000,000 shares of our common stock at an exercise price of \$0.50 per share, for an aggregate purchase price of \$10,000,000 (collectively, "the Series B Financing"). The Series B Financing consisted of \$4,703,000 of new cash investment and the capital conversion of approximately \$5,297,000 of outstanding dividends payable on our Series A Preferred Stock into shares of Series B Preferred Stock. Certain terms of the Series B Preferred Stock are senior in right to the Company's outstanding Series A Preferred Stock. The Series B Financing was approved by the requisite percentage of the holders of the Company's Series A Preferred Stock and closed on October 25, 2012.

On June 28, 2012, Dr. Ron Allison of Carolina Radiation Medicine presented interim results from our ongoing MuGard post marketing clinical trial in oral mucositis at the Multinational Association of Supportive Care in Cancer (MASCC) Conference in New York City. The presentation summarized data from 70 cancer patients undergoing mouth and throat soreness, which demonstrated a statistically significant delay to onset of oral mucositis as measured in days or cumulative radiation, and statistically significant reductions in weight loss during therapy and in the use of opioid pain medication.

On February 24, 2012, we announced that our MuGard partner in China, RHEI, received regulatory and marketing approval for MuGard from the State Food and Drug Administration to treat oral mucositis in cancer patients. Manufacturing will commence shortly in the United States to meet the demand created by Jian An, RHEI's sales and marketing partner in China.

On February 16, 2012, we announced that Children's Hospital of Colorado has added MuGard to its hospital pharmacy formulary. Children and young adults undergoing cancer treatment will now have direct access to MuGard from the first day of cancer treatment to manage oral mucositis, characterized by inflammation and erythema or ulcerations throughout the oral mucosa.

On February 10, 2012, we entered into amendment agreements for 4,581,816 currently outstanding warrants which extended the expiration dates of such warrants to February 16, 2015 for 3,818,180 warrants; to October 24, 2015 for 386,364 warrants; and to December 6, 2015 for 377,272 warrants. The holders of such warrants are SCO Capital Partners LLC, Lake End Capital LLC and Beach Capital LLC. These holders may be deemed to be affiliates of Jeffrey B. Davis, our Chief Executive Officer, and Steven H. Rouhandeh, a director, respectively, as well as other un-affiliated warrant holders. The warrants that were amended were for the purchase of an aggregate of 4,581,816 shares of our common stock. In connection with the amendments, the holders of such warrants agreed to waive any damages that they may have incurred relating to the Company's inability to register the shares of common stock issuable upon exercise of the warrants, other than liquidated damages that may have already accrued relating to such inability to register such shares.

## Corporate Information

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

## 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.

For our mucoadhesive liquid technology, used in MuGard, two U.S. patents have been issued, one European patent has been granted and one European patent application is under review. The European patent has been issued in 19 European countries. Patents have also been granted, or are under review, in several other major territories worldwide. Our mucoadhesive liquid technology patents and applications cover a range of products for a variety of diseases and conditions affecting the oral cavity, including the management of the various phases of mucositis.

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

We have two patented CobaCyte/CobOral-mediated targeted therapeutic technologies:

- two U.S. patents and several U.S. and worldwide patent applications for 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; and
- six U.S. patents and two European patents and several U.S. and worldwide patent applications for 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.

We also have intellectual property in connection with the use of other B vitamins, folic acid and biotin, used in conjunction with vitamin B12 for targeting of nanoparticles and polymer therapeutics. Enhanced tumor delivery is achieved by targeting folate receptors, which are upregulated in certain tumor types.

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

- MuGard mucoadhesive technology in 2030,
- ProLindac™ in 2021, and
- CobaCyte/CobOral mediated technology between 2013 and 2030.

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 establishes 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 Investigational New Drug ("IND") application 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, 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, and 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**

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

ActoGeniX N.V., Alder Biopharmaceuticals, Inc., Applied Protein Sciences, LLC, Avaxia Biologics, Inc, BioAlliance Pharma S.A., Camurus AB, EUSA Pharma, Galera Therapeutics, Inc. Maya Biotech Ltd. , NephRx, Piramal Healthcare Ltd., PolyMedix, Inc., Soligenix, Inc. and Synedgen are developing products to treat mucositis that may compete with our mucoadhesive liquid technology. Products which are marketed to treat mucositis are Caphosol by EUSA Pharma and Kepivance by Biovitrum.

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 U.S.; and several generic manufacturers, and
- Oxaliplatin, marketed by Sanofi-Aventis and several generic manufacturers.

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

- Regulon is developing liposomal platinum formulations;
- Nanocarrier and Debio are developing micellar nanoparticle platinum formulations; and
- Daiichi, Mersana Therapeutics, Nektar Therapeutics, Vivamer, Serina Therapeutics, SynDevRx, and Enzon are developing alternate drugs in combination with polymers and other drug delivery systems.

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

BioDelivery Sciences International, Biocon Limited, Bidel, Inc. Biovail Corporation, Diasome Pharmaceuticals, Depomed Inc., Emisphere Technologies, Inc., Eurand, Flamel Technologies, Merrion Pharmaceuticals, OraMed and Xenoport are developing products which compete with our oral drug delivery system.

Many of these competitors have greater financial and other resources, including larger research and development, marketing and manufacturing organizations. As a result, our competitors may successfully develop technologies and

drugs that are more effective or less costly than any that we are developing or which would render our technology and future products obsolete and noncompetitive.

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

### **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 generally have alternate suppliers available.

### **Employees**

As of March 19, 2013, we had eight full-time employees, one of whom has 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 audit, compensation and nominating and corporate governance committees of the Board of Directors (the "Board") and our 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

## **EXECUTIVE OFFICERS OF THE REGISTRANT**

Mr. Jeffrey B. Davis, 49 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. Previously, Mr. Davis served in a variety of senior investment banking and management positions and 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., 64, has been Senior Vice President Research and Development since January 2003 and was Vice President Research and Development from 1998 until 2003. 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.

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Mr. Stephen B. Thompson, 59, has been a 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.

### **ITEM 1A. RISK FACTORS**

#### **Risks relating to our business and industry**

##### **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, 2012, 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 \$268.0 million through December 31, 2012. Net losses allocable to common stockholders for the years ended 2012 and 2011 were \$12.5 million and \$4.3 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, 2012 was approximately \$331,000 per month. We project our cash disbursements from operations for the next twelve months to be approximately \$565,000 per month, excluding offsetting product and royalty revenues. Capital expenditures are forecasted to be minor for the next twelve months.

We require substantial capital for our development programs and operating expenses, to pursue regulatory clearances and to prosecute and defend our intellectual property rights. We believe that our existing capital resources, interest income, product sales, royalties and revenue from possible licensing agreements and collaborative agreements will be sufficient to fund our currently expected operating expenses and capital requirements into the third quarter of 2013. We will need to raise substantial additional capital to support our ongoing operations.

If we raise additional funds by issuing equity securities, further dilution to existing stockholders will 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 do not have significant operating revenue and may never attain profitability.**

To date, we have funded our 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 our operations. Our ability to achieve significant revenue or profitability depends upon our ability to successfully market MuGard in North America, Europe and China or to 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 are not expecting any significant revenues in the short-term from our products or product candidates. 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, and any amounts that we

receive under strategic partnerships and research or drug development collaborations that we may establish and, as a result, we may be unable to achieve or maintain profitability in the future or to achieve significant revenues in order to fund our operations.

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

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

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

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

Our primary focus is on our research and development activities and the commercialization of compounds covered by proprietary biopharmaceutical patents and patent applications. Research and development activities, by their nature, preclude definitive statements as to the time required and costs involved in reaching certain objectives. Actual research and development costs, therefore, could significantly exceed budgeted amounts and estimated time frames may require significant 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 and our ability to successfully commercialize, and market our product candidates could be limited if a number of these existing relationships are terminated.**

Our strategy for the research, development and commercialization of our potential pharmaceutical products may require us to enter into various arrangements with corporate and academic collaborators, licensors, licensees and others, in addition to our existing relationships with other parties. Specifically, we may seek to joint venture, sublicense or enter other marketing arrangements with parties that have an established marketing capability or we may choose to pursue the commercialization of such products on our own. We may, however, be unable to establish such additional collaborative arrangements, license agreements, or marketing agreements as we may deem necessary to develop, commercialize and market our potential pharmaceutical products on acceptable terms. Furthermore, if we maintain and establish arrangements or relationships with third parties, our business may depend upon the successful performance by these third parties of their responsibilities under those arrangements and relationships.

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 partners. Although we have had discussions with potential licensing partners with respect to our polymer platinate program, to date we have not entered into any licensing arrangement. We may be unable to execute our licensing strategy for polymer platinate.

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



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

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

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

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

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. Further, our ability to commence and/or complete development projects will be subject to our ability to raise enough funds to pay for the development costs of these projects.

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 future drug candidates may not demonstrate the safety and efficacy 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. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate. A delay or failure to receive regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in our attempt to further develop such candidates and obtain future regulatory approval.

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

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing and marketing of pharmaceutical products. These risks will expand with respect to our drug candidates, if any, that receive regulatory approval for commercial sale and we may face substantial liability for damages in the event of adverse side effects or product defects identified with any of our products that are used in clinical tests or marketed to the public. 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 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. In the event of an 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.

Many of our 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 can. Companies that complete clinical trials, obtain required regulatory agency approvals and commence commercial sale of their drugs before their competitors may achieve a significant competitive advantage. Drugs resulting from our research and development efforts or from our joint efforts with collaborative partners therefore may not be commercially competitive with our competitors' existing products or products under development.

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

We are dependent upon these licenses for our rights to develop and commercialize our product candidates. These licenses

may be terminated or converted to non-exclusive licenses by the licensor if we breach the terms of the license. We cannot guarantee you that the licenses will not be terminated or converted in the future.

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

The successful commercialization of, and the interest of potential collaborative partners to invest in the development of our drug candidates, may depend substantially upon reimbursement of the costs of the resulting drugs and related treatments at acceptable levels from government authorities, private health insurers and other organizations, including health maintenance organizations, or HMOs. Limited reimbursement for the cost of any drugs that we develop may reduce the demand for, or price of such drugs, which would hamper our ability to obtain collaborative partners to commercialize our drugs, or to obtain a sufficient financial return on our own manufacturing and commercialization of any future drugs.

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

The drugs that we are attempting to develop may compete with a number of well-established drugs manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any drugs developed by us will depend on a number of factors, including the establishment and demonstration of the clinical efficacy and safety of our drug candidates, the potential advantage of our drug candidates over existing therapies and the reimbursement policies of government and third-party payers. Physicians, patients or the medical community in general may not accept or use any drugs that we may develop independently or with our collaborative partners and if they do not, our business could suffer.

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

Lower prices for pharmaceutical products may result from:

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

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

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

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

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



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

We are highly dependent upon the efforts of our senior management and scientific team, including our President and Chief Executive Officer, Jeffrey B. Davis. The loss of the services of one or more of these individuals could delay or prevent the achievement of our research, development, marketing, or product commercialization objectives. While we have employment agreements with Jeffrey B. Davis, David P. Nowotnik, PhD our Senior Vice President Research and Development and Frank A. Jacobucci, our Vice President Sales and Marketing, their employment may be terminated by them or us at any time. We do not have employment contracts with our other key personnel. We do not maintain any "key-man" insurance policies on any of our key employees and we do not intend to obtain such insurance. In addition, due to the specialized scientific nature of our business, we are highly dependent upon our ability to attract and retain qualified scientific and technical personnel. In view of the stage of our development and our research and development programs, we have restricted our hiring to research scientists and a small administrative staff and we have made only limited investments in manufacturing, production, 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.

**We will 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 our Convertible Preferred Stock, upon exercise of certain warrants or the issuance of certain dividends.**

Pursuant to issuing Convertible Preferred Stock and warrants, we entered into an Investor Rights Agreement with the purchasers of Convertible Preferred Stock. The Investor Rights Agreement requires, among other things, that we maintain an effective registration statement for common stock issuable upon conversion of Convertible Preferred Stock or upon exercise of certain warrants. We have failed to maintain such an effective registration statement and, as a result, we may be required to pay liquidated damages to certain holders of such Convertible 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 and By-laws may make it more difficult for a third party to acquire control of us, even if a change in control would benefit our stockholders. In particular, shares of our preferred stock may be issued in the future without further stockholder approval and upon such terms and conditions, and having such rights, privileges and preferences, as our Board of Directors may determine, including, for example, rights to convert into our common stock. The rights of the holders of our common stock will be subject to, and may be adversely affected by, the rights of the holders of any of our preferred stock that may be issued in the future. The issuance of our preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire control of us. This could limit the price that certain investors might be willing to pay in the future for shares of our common stock and discourage these investors from acquiring a majority of our common stock. Further, the existence of these corporate governance provisions could have the effect of entrenching management and making it more difficult to change our management.

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

The market price for our common stock could drop as a result of sales of a large number of our presently outstanding shares or shares we may issue or be obligated to issue in the future. Substantially all of the shares of our common stock that were outstanding as of March 19, 2013, are unrestricted and freely tradable or tradable pursuant to a resale registration statement or under Rule 144 of the Securities Act or are covered by a registration rights agreement.

**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. Based on our 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, 2012, 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 ("COSO").

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

Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in our reported financial information, which could have a material adverse effect on our stock price. Failure to comply with Section 404 could also potentially subject us to sanctions or investigations by the Securities and Exchange Commission ("SEC") or other regulatory authorities.

**Risks related to our common stock**

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

The issued and outstanding shares of Convertible 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.

**If we issue certain shares of our common stock or common stock equivalents at a price below \$0.50 per share, the exercise price of certain of our outstanding warrants will be automatically lowered to the common stock issue price.**

Certain of our warrants contain a price protection mechanisms in which the exercise price of these the warrants will automatically be lowered in the event we issue certain shares of our common stock for a price less than \$0.50 per share.

**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. 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 our 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 our 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 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 71.3%, 9.6%, and 5.6%, respectively, of our common stock on an as converted basis as of March 19, 2013. 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

**ITEM 2. PROPERTIES**

We maintain one facility of approximately 9,000 square feet for administrative offices and laboratories in Dallas, Texas on a month to month lease.

We also maintain approximately 2,000 square feet of business office suites for administrative offices in New York, New York. We have a lease agreement for the facility, which terminates in August 2013.

We believe that our existing properties are suitable for the conduct of our business and adequate to meet our present needs.

**ITEM 3. LEGAL PROCEEDINGS**

Alan Schmidt, a former shareholder of Genaera Corporation ("Genaera"), and a former unitholder of the Genaera Liquidating Trust (the "Trust"), filed a purported class action in the United States District Court for the Eastern District of Pennsylvania in June, 2012. The lawsuit named thirty defendants, including the Company, MacroChem Corporation, which was acquired by the Company in February 2009, Jeffrey Davis, the CEO and a director of the Company, and Steven H. Rouhandeh and Mark Alvino, both of whom are Company executives (the "Access Defendants"). With respect to the Access Defendants, the complaint alleges direct and derivative claims asserting that directors of Genaera and the Trustee of the Trust breached their fiduciary duties to Genaera, Genaera's shareholders and the Trust's unitholders in connection with the licensing and disposition of certain assets, aided and abetted by numerous defendants including the Access Defendants. Schmidt seeks money damages, disgorgement of any distributions received from the Trust, rescission of sales made by the Trust, attorneys' and expert fees, and costs. On December 19, 2012 Schmidt filed an amended complaint which asserts substantially the same allegations with respect to the Access Defendants. On February 4, 2013, the Access Defendants moved to dismiss all claims asserted against them. Schmidt has not yet responded to the Access Defendants' motion to dismiss. The Company has advised that its intends to defend the lawsuit vigorously.

We are not currently subject to any other material pending legal proceedings.

**ITEM 4. MINE SAFETY DISCLOSURES**

Not applicable.

**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.

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 2012 and 2011. The OTCBB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

	<b>Common Stock</b>	
	<b><u>High</u></b>	<b><u>Low</u></b>
<b>Fiscal Year Ended December 31, 2012</b>		
First quarter	\$ 1.44	\$ 0.98
Second quarter	1.23	0.45
Third quarter	0.73	0.32
Fourth quarter	0.45	0.22
<b>Fiscal Year Ended December 31, 2011</b>		
First quarter	\$ 2.59	\$ 1.95
Second quarter	2.30	1.75
Third quarter	2.45	1.74
Fourth quarter	1.90	1.32

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 Series A preferred stock at the rate of 6% per year. We are also required to pay dividends on our Series B preferred stock at the rate of 12% per year.

The number of record holders of our common stock at March 19, 2013 was approximately 6,900. On March 19, 2013, the closing price for the common stock as quoted on the OTCBB was \$0.24. There were 24,732,312 shares of common stock outstanding at March 19, 2013.

## Equity Compensation Plan Information

The following table sets forth, as of December 31, 2012, information about shares of common stock outstanding and available for issuance under our existing equity compensation plans.

Plan Category	Number of securities to be issued upon exercise of outstanding options warrants and rights (a)	Weighted-average exercise price of outstanding options warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (c)
Equity compensation plans approved by security holders:			
2005 Equity Incentive Plan	2,663,784	\$1.36	1,091,702
1995 Stock Awards Plan	39,500	15.87	-
Equity compensation plans not approved by security holders:			
2007 Special Stock Option Plan	-	-	450,000
<b>Total</b>	<b>2,703,284</b>	<b>\$1.57</b>	<b>1,541,702</b>

### The 2007 Special Stock Option Plan

The 2007 Special Stock Option Plan (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 (Code). The Plan allows for the issuance of options to acquire up to 450,000 shares of our common stock none of which have been issued. The purpose of the Plan is to encourage ownership of common stock by employees, consultants, advisors and directors and to provide additional incentive for them to promote the success of our 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.

### Issuer Purchases of Equity Securities

None

### Recent Sales of Unregistered Securities

On October 25, 2012, we entered into a Preferred Stock and Warrant Purchase Agreement (the “Purchase Agreement”) with existing investors whereby we agreed to sell 1,000 shares of a newly created series of our preferred stock, designated “Series B Cumulative Convertible Preferred Stock”, par value \$0.01 per share, for an issue price of \$10,000 per share, (the “Series B Preferred Stock”) and issued warrants to purchase 20,000,000 shares of our common stock at an exercise price of \$0.50 per share, for an aggregate purchase price of \$10,000,000 (collectively, “the Series B Financing”). The Series B Financing consisted of \$4,703,000 of new cash investment and the capital conversion of approximately \$5,297,000 of outstanding dividends payable on our Series A Preferred Stock into shares of Series B Preferred Stock.

## ITEM 6. SELECTED FINANCIAL DATA

Not applicable

## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND 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 marketed product, one product in Phase 2 of clinical development and several products in pre-clinical development.

### **Results of Operations**

#### **Comparison of Years Ended December 31, 2012 and 2011**

Product sales of MuGard in the United States totaled \$2,865,000 for the year ended December 31, 2012 as compared to \$539,000 for the same period of 2011, an increase of \$2,326,000 due to increased sales and acceptance of our product. See sales table in Critical Accounting Policies and Estimates Relating to MuGard.

Our licensing revenue for the year ended December 31, 2012 was \$1,446,000 as compared to \$1,181,000 for 2011, an increase of \$265,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. In the first quarter of 2012, we finalized the negotiations for the termination of the license with SpePharm for MuGard for EU territories and recognized all of the previously received license fees (\$706,000) that were recorded in deferred revenue and a \$500,000 termination fee.

We recorded royalty revenue for MuGard in Europe of \$93,000 for the year ended December 31, 2012 as compared to \$89,000 for 2011.

Sponsored research and development revenues were \$30,000 for the year ended December 31, 2011 with no revenues for the same period of 2012. The revenues in 2011 are for research collaborations on our CobOral and CobaCyte projects.

Total research and development spending for the year ended December 31, 2012 was \$2,010,000, as compared to \$3,579,000 for 2011, a decrease of \$1,569,000. The decrease in expenses was primarily due to:

- decreased clinical development with trials for ProLindac, MuGard and Thiarabine (\$638,000);
- decreased stock compensation expense for lower expense of option grants for research and development employees (\$282,000);
- decreased scientific consulting costs (\$216,000);
- lower salary and related expenses (\$206,000) due to the shut down of our laboratory;
- lower external development expenses (\$107,000); and
- other net decreases in research spending (\$120,000).

Product costs for MuGard in the United States were \$267,000 for the year ended December 31, 2012 as compared to \$148,000 for the same period in 2011, an increase of \$119,000 due to the increased sales of our product.

Total selling, general and administrative expenses were \$6,024,000 for the year ended December 31, 2012, an increase of \$269,000 compared to the same period in 2011 of \$5,755,000. The increase in expenses was due primarily to the following:

- increased MuGard product selling expenses (\$1,343,000);
- increased professional fees (\$235,000);
- decreased general business consulting expenses due to the higher use of outside consultants in 2011 (\$821,000) versus the same period in 2012;
- decreased stock compensation expense due to lower expense of option grants for selling, general and administrative employees and directors (\$395,000); and
- decreased net other general and administrative expenses (\$93,000).

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Depreciation and amortization was \$419,000 for the year ended December 31, 2012 as compared to \$233,000 for 2011, an increase of \$186,000. Patents related to the 2012 terminated Thiarabine project were further amortized \$291,000. Assets related to the laboratory which was shut down in 2012 were further depreciated \$29,000. All of the patents have been fully amortized and most of the assets are fully depreciated.

Total operating expenses for the year ended December 31, 2012 were \$8,720,000 as compared to total operating expenses of \$9,715,000 for 2011, a decrease of \$995,000 for the reasons listed above.

Interest and miscellaneous income was \$242,000 for the year ended December 31, 2012 as compared to \$1,334,000 for 2011, a decrease of \$1,092,000. Miscellaneous income was higher in 2011 due to negotiated payables and write-offs of other accounts payable that occurred in 2011.

Interest and other expense was \$608,000 for the year ended December 31, 2012 as compared to \$963,000 in 2011, a decrease of \$355,000. The decrease in interest and other expense was due to the repayment in full of the secured promissory note of \$2.75 million plus accrued interest.

We recorded an expense of \$2,316,000 in the first quarter of 2012 for amendment agreements for 4,581,816 currently outstanding warrants which extended the expiration dates of such warrants to February 16, 2015 for 3,818,180 warrants; to October 24, 2015 for 386,364 warrants; and to December 6, 2015 for 377,272 warrants. The holders of such warrants include unaffiliated warrant holders as well as SCO Capital Partners LLC, Lake End Capital LLC and Beach Capital LLC. Such holders may be deemed to be affiliates of Jeffrey B. Davis and Steven H. Rouhandeh, our Chief Executive Officer and a director, respectively. The warrants that were amended were for the purchase of an aggregate of 4,581,816 shares of our common stock. In connection with the amendments, the holders of such warrants agreed to waive any damages that they may have incurred relating to the Company's inability to register the shares of common stock issuable upon exercise of the warrants, other than liquidated damages that may have already accrued relating to such inability to register such shares.

We recorded a gain related to warrants classified as derivative liabilities of \$1,236,000 for the year ended December 31, 2012 as compared to \$3,580,000 for the same period of 2011. We recorded a derivative for warrants in 2009 when the fair value of the warrants that were issued with our Series A Convertible Preferred Stock were reclassified from equity per the requirements of accounting guidance as a result of the repricing feature.

We recorded a loss for the derivative liability related to preferred stock of \$4,770,000 for the year ended December 31, 2012 and a gain of \$1,410,000 for the same period of 2011. We recorded a derivative in 2010 per the requirements of accounting guidance due to the possibility of repricing our Series A Convertible Preferred Stock if we sold our common stock at a price below the original conversion price.

Preferred stock dividends of \$1,999,000 were accrued for the year ended December 31, 2012 and \$1,774,000 for 2011, an increase of \$225,000.

Net loss allocable to common stockholders for the year ended December 31, 2012 was \$12,531,000, or a \$0.52 basic and diluted loss per common share, compared with net loss of \$4,306,000, or a \$0.22 basic and diluted loss per common share for the same period in 2011, an increased loss of \$8,225,000.

### **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. Product sales and royalty revenues provided limited funding for operations during the year ended December 31, 2012. As of December 31, 2012, our cash and cash equivalents were \$396,000 and our net cash burn rate for the year ended December 31, 2012, was approximately \$331,000 per month. As of December 31, 2012, our working capital deficit was \$4,948,000. Our working capital deficit at December 31, 2012 represented an increase of \$3,929,000 as compared to our working capital deficit as of December 31, 2011 of \$8,877,000. The increase in the working capital deficit at December 31, 2012 reflects twelve months of net operating costs, repayment of \$2.75 million of the outstanding loan offset by \$4,654,000 net proceeds from the October 2012 private placement of Series B preferred stock.

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As of March 18, 2013, we did not have enough capital to achieve our long-term goals. If we raise additional funds by selling equity securities, the relative equity ownership of our existing investors will 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 and our ability to continue as a going concern.

We have 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, 2012 of \$267,972,000. We expect that our capital resources, revenues from MuGard sales and expected receipts due under our license agreements will be adequate to fund our current level of operations into the third quarter of 2013. 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 are 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.

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 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, 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)	Twelve Months ended		Inception To Date (1)
	December 31,		
Project	2012	2011	
Polymer Platinite (ProLindac™)	\$ 505	\$ 1,618	\$ 32,946
MuGard	1,033	1,310	4,290
Others (2)	472	651	6,883
Total	\$ 2,010	\$ 3,579	\$ 44,119



- (1) Cumulative spending from inception of the Company or project through December 31, 2012.
- (2) Includes: CobOral, CobaCyte and other 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.

We do not believe inflation or changing prices have had a material impact on our revenue or operating income in the past three years.

### **Climate Change**

We do not believe there is anything unique to our business which would result in climate change regulations having a disproportional effect on us as compared to U.S. industry overall.

### **Critical Accounting Policies and Estimates**

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the U.S. 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, 2012 were fully amortized or impaired. At December 31, 2011 they consisted primarily of patents acquired in acquisitions and licenses which were recorded at fair value on the acquisition date.

#### *Receivables*

Receivables are reported in the balance sheets at the outstanding amount net of an allowance for doubtful accounts. We continually evaluate the creditworthiness of our customers and their financial condition and generally do not require collateral. The allowance for doubtful accounts is based upon reviews of specific customer balances, historic losses, and general economic conditions. As of December 31, 2012 and 2011, no allowance was recorded as all accounts are considered collectible.

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### *Product sales and allowances*

We sell MuGard to wholesalers, and specialty and retail pharmacies. We began shipping to customers in September 2010.

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers, rebates or discounts taken. If actual future results vary from our estimates, we may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. Our product sales allowances include:

- Wholesaler and Specialty and Retail Pharmacy Discounts – we offer contractually determined discounts to certain wholesale distributors and specialty and retail pharmacies that purchase directly from us. These discounts are either taken off the invoice at the time of shipment or paid to the customer on a monthly or quarterly basis.
- Prompt Pay Discounts – we offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. Based on our experience many of the customers comply with the payment terms to earn the cash discount.
- Patient Discount Programs – we offer discount card programs in which patients receive certain discounts off their prescription.
- Managed Care Rebates – we offer discounts under contracts with certain managed care providers who do not purchase directly from us.

We believe our estimates related to gross-to-net sales adjustments for MuGard do not have a high degree of estimation complexity or uncertainty as the related amounts are settled within a short period of time.

(in thousands)	Three months ended March 31, 2012	Three months ended June 30, 2012	Three months ended Sept 30, 2012	Three months ended Dec 31, 2012	Twelve months ended December 31, 2012
Gross sales	\$ 577	\$ 712	\$ 877	\$ 1,048	\$ 3,214
Cash discounts	5	13	7	9	34
Contract discounts	18	84	89	124	315
	<u>\$ 554</u>	<u>\$ 615</u>	<u>\$ 781</u>	<u>\$ 915</u>	<u>\$ 2,865</u>

	Three months ended March 31, 2011	Three months ended June 30, 2011	Three months ended Sept 30, 2011	Three months ended Dec 31, 2011	Twelve months ended December 31, 2011
Gross sales	\$ 13	\$ 43	\$ 82	\$ 410	\$ 548
Cash discounts	-	1	-	1	2
Contract discounts	-	-	-	7	7
	<u>\$ 13</u>	<u>\$ 42</u>	<u>\$ 82</u>	<u>\$ 402</u>	<u>\$ 539</u>

### *License Revenues and Royalties*

Our revenues are generated from licensing, research and development agreements, royalties and product sales. 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. Royalties are recognized in the period of sales.

### *Cost of product sales*

Cost of product sales consists of costs of the contract manufacturing, product costs and packaging costs, product quality testing, distribution costs and shipping costs related to our product sales of MuGard.

### *Stock Based Compensation Expense*

We account for stock based compensation expense in accordance with FASB ASC 718, *Stock Based Compensation*. We have several stock-based compensation plans under which incentive and non-incentive qualified stock options and restricted shares may be granted to employees, directors and consultants. We measure the cost of the employee/director/consultant services received in exchange for an award of equity instruments based on the grant date fair value of the award. We use the Black-Scholes option pricing model to value our options.





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Stock-based compensation expense recognized for the years ended December 31, 2012 and 2011 was approximately \$1,066,000 and \$1,066,000, respectively.

**Off-Balance Sheet Transactions**

None.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable

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

Financial statements required by this Item are incorporated in this Annual Report Form 10-K on pages F-1 through F-23 hereto. 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. CONTROLS AND PROCEDURES**

Under the supervision and with the participation of our management, including the Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal 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 Disclosure 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 SEC’s rules and forms. Disclosure Controls are also designed to provide reasonable assurance that such information is accumulated and communicated to our management, including our 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 Annual 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 were not effective.

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

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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 COSO in Internal Control—Integrated Framework.

Based on our 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.

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, 2012, our internal control over financial reporting was not effective based on the criteria established in Internal Control-Integrated Framework issued by COSO.

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 rules of the SEC that permit smaller reporting companies like us 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, 2012 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 2013 Proxy Statement to be filed with the U.S. Securities and Exchange Commission in connection with the solicitation of proxies for our 2013 Annual Meeting of Shareholders (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. We 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”. We 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 is 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 is 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 is contained in the Proxy Statement and is incorporated herein by reference.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

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

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

	<u>Page</u>
a. <u>Financial Statements</u> . The following financial statements are submitted as part of this report:	
<a href="#">Report of Independent Registered Public Accounting Firm</a>	<a href="#">F-1</a>
<a href="#">Consolidated Balance Sheets at December 31, 2012 and 2011</a>	<a href="#">F-2</a>
<a href="#">Consolidated Statements of Operations for 2012 and 2011</a>	<a href="#">F-3</a>
<a href="#">Consolidated Statements of Stockholders' Deficit for 2012 and 2011</a>	<a href="#">F-4</a>
<a href="#">Consolidated Statements of Cash Flows for 2012 and 2011</a>	<a href="#">F-5</a>
<a href="#">Notes to Consolidated Financial Statements</a>	<a href="#">F-6</a>
b. <u>Exhibits</u>	
<u>Exhibit</u>	
<u>Number</u> <u>Description of Document</u>	
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)



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- 3.12 Certificate of Designations, Rights and Preferences of Series B Cumulative Convertible Preferred Stock filed October 26, 2012 (Incorporated by reference to Exhibit 10.3 of our Form 8-K filed October 26, 2012)
- 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 HEMA 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\* 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10-K for the year ended December 31, 1999)
- 10.6\* 2005 Equity Incentive Plan (Incorporated by reference to Exhibit 1 of our Proxy Statement filed on April 18, 2005)
- 10.7 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)
- 10.8 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)
- 10.9 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)
- 10.10 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)
- 10.11 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)
- 10.12 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)
- 10.13\* 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)
- 10.14 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)
- 10.15 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)
- 10.16 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)
- 10.17 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)
- 10.18 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)
- 10.19 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)
- 10.20 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)
- 10.21\* 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)
- 10.22 Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.29 of our Form S-1 filed on January 15, 2010)
- 10.23 Form of Warrant (Incorporated by reference to Exhibit 10.30 of our Form S-1 filed on January 15, 2010)
- 10.24 Form of Securities Purchase Agreement dated as of December 10, 2010 by and among us and the Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on December 14, 2010)
- 10.25 Form of Common Stock Warrant issued by us (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on December 14, 2010)
- 10.26 Form of Securities Purchase Agreement dated as of November 1, 2011 by and among us and the Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on November 10, 2011)



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- 10.27 Form of Common Stock Warrant (Two and One Half Year Warrant) issued by us (Incorporated by reference to Exhibit 10.2 of our Form 8-K filed on November 10, 2011)
- 10.28 Form of Common Stock Warrant (Five Year Warrant) issued by us (Incorporated by reference to Exhibit 10.3 of our Form 8-K filed on November 10, 2011)
- 10.29 Amendment No.1 to Warrant Agreement dated February 10, 2012 by and among us and warrant holders including certain affiliates named therein extending the term of certain warrants until 2015 (Incorporated by reference to Exhibit 99.1 of our Form 8-K filed on February 10, 2012)
- 10.30 Preferred Stock and Warrant Purchase Agreement dated October 25, 2012 by and among us and the Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed October 26, 2012)
- 10.30 Preferred Stock and Warrant Purchase Agreement dated October 25, 2012 by and among us and the Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed October 26, 2012)
- 10.31 Investor Rights Agreement dated October 25, 2012, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.2 of our Form 8-K filed on October 26, 2012)
- 10.32 Form of Common Stock Warrant issued by us (Incorporated by reference to Exhibit 10.3 of our Form 8-K filed on October 26, 2012)
- 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 and 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
- 101\*\*\*The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2012 for the fiscal year ended December 31, 2012, formatted in XBRL (Extensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' Deficit, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements, tagged as blocks of text.

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

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

\*\*\* This exhibit is deemed to be furnished and not filed.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACCESS PHARMACEUTICALS, INC.

Date March 19, 2013                      By:           /s/ Jeffrey B. Davis            
Jeffrey B. Davis  
Chief Executive Officer

Date March 19, 2013                      By:           /s/ Stephen B. Thompson            
Stephen B. Thompson  
Vice President, Chief Financial  
Officer and Treasurer  
Principal Financial and Accounting  
Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Date March 19, 2013                      By:           /s/ Jeffrey B. Davis            
Jeffrey B. Davis, Director  
Chief Executive Officer  
Principal Executive Officer

Date March 19, 2013                      By:           /s/ Stephen B. Thompson            
Stephen B. Thompson  
Vice President, Chief Financial  
Officer and Treasurer  
Principal Financial and Accounting  
Officer

Date March 19, 2013                      By:           /s/ Mark J. Ahn            
Mark J. Ahn, Director

Date March 19, 2013                      By:           /s/ Mark J. Alvino            
Mark J. Alvino, Director

Date March 19, 2013                                /s/ Stephen B. Howell            
Stephen B. Howell, Director

Date March 19, 2013                      By:           /s/ Steven H. Rouhandeh            
Steven H. Rouhandeh, Chairman of  
the Board

## **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, 2012 and 2011, and the related consolidated statements of operations, stockholders' 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 consolidated 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 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Access Pharmaceuticals, Inc. and subsidiaries as of December 31, 2012 and 2011, 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 19, 2013

**Access Pharmaceuticals, Inc. and Subsidiaries**

CONSOLIDATED BALANCE SHEETS

ASSETS	December 31, 2012	December 31, 2011
Current assets		
Cash and cash equivalents	\$ 396,000	\$ 2,460,000
Receivables	840,000	333,000
Inventory	194,000	151,000
Restricted cash	-	330,000
Prepaid expenses and other current assets	251,000	39,000
Total current assets	1,681,000	3,313,000
Property and equipment, net	7,000	51,000
Patents, net	-	362,000
Other assets	42,000	59,000
Total assets	\$ 1,730,000	\$ 3,785,000
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	\$ 2,039,000	\$ 1,713,000
Accrued expenses	857,000	857,000
Dividends payable	3,486,000	6,487,000
Accrued interest payable	-	98,000
Debt, current portion	-	2,750,000
Current portion of deferred revenue	247,000	285,000
Total current liabilities	6,629,000	12,190,000
Derivative liability - warrants	271,000	1,507,000
Derivative liability - preferred stock	9,200,000	4,430,000
Long-term deferred revenue	2,706,000	3,264,000
Total liabilities	18,806,000	21,391,000
Commitments and contingencies		
Stockholders' deficit		
Convertible preferred stock A - \$.01 par value; authorized 2,000,000 shares; 2,913.3617 issued at December 31, 2012; 2,938.3617 issued at December 31, 2011		
Convertible preferred stock B - \$.01 par value; authorized 2,000,000 shares; 1,000.0 issued at December 31, 2012; none issued at December 31, 2011	-	-
Common stock - \$.01 par value; authorized 130,000,000 shares; issued 24,732,312 at December 31, 2012; issued 23,890,787 at December 31, 2011	247,000	239,000
Additional paid-in capital	250,653,000	237,600,000
Treasury stock, at cost – 163 shares	(4,000)	(4,000)
Accumulated deficit	(267,972,000)	(255,441,000)
Total stockholders' deficit	(17,076,000)	(17,606,000)
Total liabilities and stockholders' deficit	\$ 1,730,000	\$ 3,785,000

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



**Access Pharmaceuticals, Inc. and Subsidiaries**

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the year ended December 31,	
	2012	2011
<b>Revenues</b>		
Product sales	2,865,000	539,000
License revenues	\$ 1,446,000	\$ 1,181,000
Royalties	93,000	89,000
Sponsored research and development	-	30,000
<b>Total revenues</b>	<b>4,404,000</b>	<b>1,839,000</b>
<b>Expenses</b>		
Research and development	2,010,000	3,579,000
Product costs	267,000	148,000
Selling, general and administrative	6,024,000	5,755,000
Depreciation and amortization	419,000	233,000
<b>Total expenses</b>	<b>8,720,000</b>	<b>9,715,000</b>
Loss from operations	(4,316,000)	(7,876,000)
Interest and miscellaneous income	242,000	1,334,000
Interest and other expense	(608,000)	-
Warrant extension expense	(2,316,000)	(963,000)
Gain on change in fair value of derivative-warrants	1,236,000	3,580,000
Gain (loss) on change in fair value of derivative-preferred stock	(4,770,000)	1,410,000
	(6,216,000)	5,361,000
Net loss before state income taxes	(10,532,000)	(2,515,000)
State income taxes	-	17,000
Net loss	(10,532,000)	(2,532,000)
Less preferred stock dividends	(1,999,000)	(1,774,000)
<b>Net loss allocable to common stockholders</b>	<b>\$ (12,531,000)</b>	<b>\$ (4,306,000)</b>
<b>Basic and diluted loss per common share</b>		
Net loss allocable to common stockholders	\$ (0.52)	\$ (0.22)
<b>Weighted average basic and diluted common shares outstanding</b>		
	24,178,768	19,983,210

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



2012	24,732,312	\$247,000	2,913.3617	\$-	1,000.00	\$-	\$250,653,000	\$(4,000)	\$(267,972,000)
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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,	
	2012	2011
<b>Cash flows from operating activities:</b>		
Net loss	\$ (10,532,000.00)	\$ (2,532,000.00)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain on change in fair value of derivative-warrants	(1,236,000.00)	(3,580,000.00)
(Gain) loss on change in fair value of derivative-preferred stock	4,770,000.00	(1,410,000.00)
Warrant extension expense	2,316,000.00	-
Gain on negotiated payables	(241,000.00)	(1,324,000.00)
Depreciation and amortization	419,000.00	233,000.00
Stock option compensation expense	390,000.00	1,066,000.00
Stock issued to directors and employees	305,000.00	-
Stock and warrants issued for services	77,000.00	602,000.00
Change in operating assets and liabilities:		
Receivables	(507,000.00)	685,000.00
Inventory	(43,000.00)	(151,000.00)
Prepaid expenses and other current assets	(212,000.00)	31,000.00
Restricted cash	330,000.00	(330,000.00)
Other assets	17,000.00	(15,000.00)
Accounts payable and accrued expenses	567,000.00	53,000
Dividends payable	319,000.00	271,000.00
Accrued interest payable	(98,000.00)	(28,000.00)
Deferred revenue	(596,000.00)	(1,180,000.00)
Net cash used in operating activities	<u>(3,955,000.00)</u>	<u>(7,609,000.00)</u>
<b>Cash flows from investing activities:</b>		
Capital expenditures	(13,000.00)	(40,000.00)
Net cash used in investing activities	<u>(13,000.00)</u>	<u>(40,000.00)</u>
<b>Cash flows from financing activities:</b>		
Payment of debt	(2,750,000.00)	(2,750,000.00)
Proceeds from preferred stock issuances, net of costs	4,654,000.00	5,826,000.00
Net cash provided by financing activities	<u>1,904,000.00</u>	<u>3,076,000.00</u>
Net decrease in cash and cash equivalents	(2,064,000.00)	(4,573,000.00)
Cash and cash equivalents at beginning of year	2,460,000.00	7,033,000.00
Cash and cash equivalents at end of year	<u>\$ 396,000.00</u>	<u>\$ 2,460,000.00</u>
<i>Supplemental cash flow information:</i>		
Cash paid for interest	388,000.00	720,000.00
<i>Supplemental disclosure of noncash transactions</i>		
Shares issued for dividends on preferred stock	\$ 22,000.00	\$ 1,000.00
Warrants issued for placement agent fees	-	39,000.00
Preferred stock dividends in dividends payable	1,999,000.00	1,774,000.00
Dividends payable exchanged for preferred stock	5,297,000.00	-

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, 2012

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

Nature of Operations

Access Pharmaceuticals, Inc. (the “Company”, “we”, “our”, or “Access”) 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.

Certain amounts have been reclassified to conform with current period classification.

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 and our wholly-owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

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.

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, 2012 and 2011, we had no such investments. We maintain deposits primarily in two financial institutions, 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.

Receivables

Receivables are reported in the balance sheets at the outstanding amount net of an allowance for doubtful accounts. We continually evaluate the creditworthiness of our customers and their financial condition and generally do not require collateral. The allowance for doubtful accounts is based upon reviews of specific customer balances, historic losses, and general economic conditions. As of December 31, 2012 and 2011, no allowance was recorded as all accounts are considered collectible.

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.

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, 2012</u>		<u>December 31, 2011</u>	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
Amortizable intangible assets - Patents	\$ 2,624	\$ 2,624	\$ 2,624	\$ 2,262

Amortization expense related to intangible assets totaled \$362,000 and \$212,000 for the years ended December 31, 2012 and 2011, respectively. Patent costs related to Thiarabine in the amount of \$291,000 were written off in the fourth quarter.

Product Sales and Allowances

We sell MuGard to wholesalers, and specialty and retail pharmacies. We began shipping to customers in September 2010. We recognize revenue for MuGard product sales at the time title transfers to our customers, which occurs at the time product is shipped to our customers.

We recognize product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers, rebates or discounts taken. If actual future results vary from our estimates, we may need to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustment. Our product sales allowances include:

- Wholesaler and Specialty and Retail Pharmacy Discounts – we offer contractually determined discounts to certain wholesale distributors and specialty and retail pharmacies that purchase directly from us. These discounts are either taken off the invoice at the time of shipment or paid to the customer on a monthly or quarterly basis.
- Prompt Pay Discounts – we offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. Based on our experience many of the customers comply with the payment terms to earn the cash discount.
- Patient Discount Programs – we offer discount card programs in which patients receive certain discounts off their prescription.
- Managed Care Rebates – we offer discounts under contracts with certain managed care providers who do not purchase directly from us.

We believe our estimates related to gross-to-net sales adjustments for MuGard do not have a high degree of estimation complexity or uncertainty as the related amounts are settled within a short period of time.

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Below is a table showing gross sales and net sales by quarter for the years ended December 31, 2012 and 2011.

(in thousands)	Three months ended March 31, 2012	Three months ended June 30, 2012	Three months ended Sept 30, 2012	Three months ended Dec 31, 2012	Twelve months ended Dec 31, 2012
Gross sales	\$ 577	\$ 712	\$ 877	\$ 1,048	\$ 3,214
Cash discounts	5	13	7	9	34
Contract discounts	18	84	89	124	315
Net Sales	<u>\$ 554</u>	<u>\$ 615</u>	<u>\$ 781</u>	<u>\$ 915</u>	<u>\$ 2,865</u>

	Three months ended March 31, 2011	Three months ended June 30, 2011	Three months ended Sept 30, 2011	Three months ended Dec 31, 2011	Twelve months ended Dec 31, 2011
Gross sales	\$ 13	\$ 43	\$ 82	\$ 410	\$ 548
Cash discounts	-	1	-	1	2
Contract discounts	-	-	-	7	7
Net Sales	<u>\$ 13</u>	<u>\$ 42</u>	<u>\$ 82</u>	<u>\$ 402</u>	<u>\$ 539</u>

### License Revenues and Royalties

Our revenues are generated from licensing, research and development agreements, royalties and product sales. 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. Royalties are recognized in the period of sales.

### Research and Development Expenses

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.

### Cost of product sales

Cost of product sales consists of costs of the contract manufacturing, product costs and packaging costs, product quality testing, distribution costs and shipping costs related to our product sales of MuGard.

### Selling, general and administrative expense

Selling, general and administrative expenses primarily consist of personnel, contract personnel, marketing and promotion expenses associated with MuGard, personnel expenses to support our administrative and operating activities, facility costs and professional expenses (i.e., legal expenses), and investor relations fees.

### Other Income

In 2012 and 2011, we recognized miscellaneous income of \$241,000 and \$1,324,000, respectively, due to negotiated payables and write-offs of other accounts payable.

### Fair Value of Financial Instruments

We calculate the fair value of our assets and liabilities which qualify as financial instruments and include additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of accounts receivable, accounts payable and accrued expenses and dividends payable approximate their carrying amounts due to the relatively short maturity of these instruments. The carrying value of the debt approximates fair value since this instrument bears market interest rates.

We consider the conversion options and warrants related to our Series A Cumulative Convertible Preferred Stock to be derivatives, and we record the fair value of the derivative liabilities in our consolidated balance sheets. Changes in the fair value of the derivative liabilities are included in gain or loss on change in fair value of derivative in the consolidated statements of operations.



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.

We account for uncertain income tax positions in accordance with FASB ASC 740, *Income Taxes*. 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, 2012 and 2011, we did not recognize any uncertain tax positions or 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, preferred stock 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 years. Anti-dilutive common stock equivalents of 116,704,461 and 38,854,446 were excluded from the loss per share computation for 2012 and 2011, respectively.

Stock-Based Compensation

We account for stock based compensation expense in accordance with FASB ASC 718, *Stock Based Compensation*. We have several stock-based compensation plans under which incentive and non-incentive qualified stock options and restricted shares may be granted to employees, directors and consultants. We measure the cost of the employee/director/consultant services received in exchange for an award of equity instruments based on the grant date fair value of the award. We use the Black-Scholes option pricing model to value our options.

During 2012 and 2011, 1,235,000 stock options and 580,000 stock options, respectively, were granted under the 2005 Equity Incentive Plan. Assumptions for 2012 and 2011 are:

	2012	2011
Expected volatility assumption was based upon a combination of historical stock price volatility measured on a weekly basis and is considered a reasonable indicator of expected volatility.	98%	117%
Risk-free interest rate assumption is based upon U.S. Treasury bond interest rates appropriate for the term of the our employee stock options.	0.45%	1.42%
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 as we do not have sufficient information to calculate an expected term.	5.5 years	5.6 years

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At December 31, 2012, 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 \$558,000. The weighted-average 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 following table summarizes stock-based compensation for the years ended December 31, 2012 and 2011 which was allocated as follows (in thousands):

	Year ended December 31, 2012	Year ended December 31, 2011
Research and development	\$ 93	\$ 377
General and administrative	297	689
Stock-based compensation expense included in operating expense	<u>390</u>	<u>1,066</u>
Total stock-based compensation expense	390	1,066
Tax benefit	-	-
Stock-based compensation expense, net of tax	<u>\$ 390</u>	<u>\$ 1,066</u>

**NOTE 2 – LIQUIDITY**

The accompanying consolidated financial statements have been prepared assuming that we are a going concern. We incurred a net loss in the years ended December 31, 2012 and 2011.

Management believes that our current cash and expected license fees should fund our expected burn rate into the third quarter of 2013. We will require additional funds to continue operations. These funds are expected to come from the future sales of equity and/or license agreements.

We have 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, 2012 of \$267,972,000. We expect that our capital resources, revenues from MuGard sales and expected receipts due under our license agreements will be adequate to fund our current level of operations into the third quarter of 2013. 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 are 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.

**NOTE 3 - RELATED PARTY TRANSACTIONS**

On occasion we may engage in certain related party transactions. Pursuant to our Audit Committee charter, our policy is that all related party transactions are reviewed and approved by the Board of Directors or Audit Committee prior to our entering into any related party transactions.



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In the event SCO Capital Partners LLC (SCO) and its affiliates were to convert all of their shares of Series A Preferred Stock, Series B Preferred Stock and exercise all of their warrants, they would own approximately 71.3% of the voting securities of Access. During 2012 and 2011, SCO and affiliates charged \$300,000 each year in investor relations fees.

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.

Dr. Esteban Cvitkovic, a former director, also served as a consultant and Senior Director, Oncology Clinical Research & Development, from August 2007 to May 2012. Dr. Cvitkovic received payments for consulting expenses and reimbursement of direct expenses. In March 2011, Dr. Cvitkovic also received 35,000 shares of our common stock valued at \$71,000 for his consulting services in 2011. Dr. Cvitkovic received no consulting fees in 2012. Dr. Cvitkovic's payments for consulting services and expense reimbursements are as follows:

<u>Year</u>	<u>Consulting Fees</u>	<u>Expense Reimbursement</u>	<u>Fair Value of Restricted Stock</u>
2011	\$ 139,000	\$ 14,000	\$ 71,000

**NOTE 4 - PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:	December 31,	
	2012	2011
Laboratory equipment	\$ 818,000	\$ 816,000
Laboratory and building improvements	17,000	6,000
Furniture and equipment	63,000	63,000
	898,000	885,000
Less accumulated depreciation and amortization	891,000	834,000
Property and equipment, net	\$ 7,000	\$ 51,000

Depreciation and amortization on property and equipment was \$57,000 and \$21,000 for the years ended December 31, 2012 and 2011, respectively. The laboratory equipment is currently being sold and has no further value to the Company. \$29,000 of further depreciation was recorded in the fourth quarter of 2012.

**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 (\$17,000 in 2012 and \$16,500 in 2011) and to have the amount of such reduction contributed to the 401(k) Plan. We had a 401(k) matching program whereby we contributed for each dollar a participant contributes a like amount, with a maximum contribution of 4% of a participant's earnings in the first eleven months of 2011. The Company suspended matching on December 1, 2011. 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 85 investment options. Company contributions under the 401(k) Plan were approximately \$0 in 2012 and \$40,000 in 2011.

## **NOTE 6 – DEBT**

We had a note payable of \$2,750,000 at December 31, 2011 which was due on September 13, 2012. The note and interest due was paid in full on November 2, 2013. The note had interest at 12% per annum with \$330,000 of interest due on September 13<sup>th</sup>. The interest due of \$330,000 was in an escrow account for the noteholder at December 31, 2011.

## **NOTE 7 – COMMITMENTS AND CONTINGENCIES**

### Operating Leases

At December 31, 2012, we had commitments under non-cancelable operating leases for our New York office until August 31, 2013 totaling \$130,000. Rent expense for the years ended December 31, 2012 and 2011 was \$288,000 and \$266,000, respectively. We also have one non-cancelable operating lease – for a copier with future obligations totaling approximately \$29,000 ending in 2014.

### Legal

Alan Schmidt, a former shareholder of Genaera Corporation (“Genaera”), and a former unitholder of the Genaera Liquidating Trust (the “Trust”), filed a purported class action in the United States District Court for the Eastern District of Pennsylvania in June, 2012. The lawsuit named thirty defendants, including the Company, MacroChem Corporation, which was acquired by the Company in February 2009, Jeffrey Davis, the CEO and a director of the Company, and Steven H. Rouhandeh and Mark Alvino, both of whom are Company executives (the “Access Defendants”). With respect to the Access Defendants, the complaint alleges direct and derivative claims asserting that directors of Genaera and the Trustee of the Trust breached their fiduciary duties to Genaera, Genaera’s shareholders and the Trust’s unitholders in connection with the licensing and disposition of certain assets, aided and abetted by numerous defendants including the Access Defendants. Schmidt seeks money damages, disgorgement of any distributions received from the Trust, rescission of sales made by the Trust, attorneys’ and expert fees, and costs. On December 19, 2012 Schmidt filed an amended complaint which asserts substantially the same allegations with respect to the Access Defendants. On February 4, 2013, the Access Defendants moved to dismiss all claims asserted against them. Schmidt has not yet responded to the Access Defendants’ motion to dismiss. The Company has advised that it intends to defend the lawsuit vigorously.

We are not currently subject to any other material pending legal proceedings.

## **NOTE 8 - FAIR VALUE MEASUREMENTS**

We calculate the fair value of our assets and liabilities which qualify as financial instruments and include additional information in the notes to the consolidated financial statements when the fair value is different than the carrying value of these financial instruments. The estimated fair value of accounts receivable, accounts payable and accrued expenses and dividends payable approximate their carrying amounts due to the relatively short maturity of these instruments. The carrying value of the debt approximates fair value since this instrument bears market interest rates.

Generally Accepted Accounting Principles define's fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

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- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

The guidance requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value.

We have segregated all financial assets and liabilities that are measured at fair value on a recurring basis (at least annually) into the most appropriate level within the fair value hierarchy based on the inputs used to determine the fair value at the measurement date in the table below.

Financial assets and liabilities measured at fair value on a recurring basis as of December 31, 2012 and December 31, 2011 are summarized below:

(in thousands)

Description	As of December 31, 2012	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability-					
warrants	\$ 271	\$ -	\$ 271	\$ -	\$ 1,236
preferred stock	\$ 9,200	\$ -	\$ -	\$ 9,200	\$ (4,770)

(in thousands)

Description	As of December 31, 2011	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability-					
warrants	\$ 1,507	\$ -	\$ 1,507	\$ -	\$ 3,580
preferred stock	\$ 4,430	\$ -	\$ -	\$ 4,430	\$ 1,410

In order to calculate the Level 3 Derivative liability - preferred stock, we used the Monte Carlo simulation to estimate future stock prices. The use of valuation techniques requires the Company to make various key assumptions for inputs into the model, including assumptions about the expected future volatility of the price of the Company's stock. In estimating the fair value at December 31, 2012, we based our selected volatility on the one-year historic volatility of the Company's stock as we believe this is most representative of the expected volatility in the near future for the Company.

**NOTE 9 – PREFERRED STOCK**

Series A Cumulative Convertible Preferred Stock

On November 7, 2007, and February 4, 2008, we entered into securities purchase agreements (the Purchase Agreements) with accredited investors to sell 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 shares of our common stock at an exercise price of \$3.50 per share. The shares of Series A Preferred Stock were convertible into common stock at the initial conversion price of \$3.00 per share. The exercise and conversion price have changed, as described below.

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.

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. Under these terms, should Access issue additional shares of common stock, in certain circumstances, for a price below \$3.00 per share, the conversion price of the Series A Preferred Stock will be lowered to the lowest subsequent issue price below \$3.00 per share until the shares are converted or redeemed. This will have the effect of diluting the holders of our common stock. Under the terms of the Purchase Agreement, should Access issue additional shares of common stock, in certain circumstances, for a price below \$3.50 per share, the exercise price of the warrants will be lowered to the lowest subsequent issue price below \$3.50 per share until the warrants are exercised or expire. Additionally, as discussed below, if we are unable to maintain an effective registration statement related to the Series A Preferred Stock, we would be required to pay liquidating damages.

On October 25, 2012, we issued Series B Preferred Stock with a conversion into common stock at \$0.50 per share in a private placement offering. Per the terms of the agreement with the outstanding Series A Preferred Stock holders their stock is now converted into shares of common stock at \$0.50 per share. The Series A Preferred Stock at December 31, 2012 was convertible into 58,267,234 shares of common stock, an increase of 38,002,683 shares of common stock from December 31, 2011.

On November 10, 2011, we issued common stock in a private placement offering at \$1.45 per share. Per the terms of the agreement with the outstanding Series A Preferred Stock holders their stock is now converted into shares of common stock at \$1.45 per share. The Series A Preferred Stock at December 31, 2011 was convertible into 20,264,551 shares of common stock, an increase of 8,584,715 shares of common stock from December 31, 2010.

In addition, warrants to acquire 4,149,464 shares of common stock that were granted to the holders of Series A Preferred Stock were re-priced from \$3.50 to \$3.00 due to the offering on January 26, 2010; then re-priced from \$3.00 to \$2.55 due to the offering on December 14, 2010; then re-priced from \$2.55 to \$1.45 due to the offering on November 10, 2011; and further re-priced from \$1.45 to \$0.50 due to the offering on October 25, 2012.

#### November 7, 2007 Series A Preferred Stock

On November 7, 2007, we entered into the Purchase Agreements with accredited investors whereby we agreed to sell 954,0001 shares of a newly created series of our 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. Due to the offering on October 25, 2012, the conversion price changed to \$0.50 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. 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. This represented 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.

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 \$2.59 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 110% and a term of 6 years.

#### February 4, 2008 Preferred Stock

On February 4, 2008, we entered into Purchase Agreements with accredited investors whereby we agreed to sell 272.50 shares of our 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. Due to the offering on October 25, 2012 the conversion price changed to \$0.50 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 option 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.

#### Derivative Liability

Effective January 1, 2009, we adopted the provisions of FASB ASC 815, "*Derivatives and Hedging*" (FASB ASC 815) (previously EITF 07-5, "*Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity's Own Stock*"). As a result of adopting FASB ASC 815, warrants to purchase 3,895,047 of our common stock previously treated as equity pursuant to the derivative treatment exemption were no longer afforded equity treatment. These warrants have an exercise price of \$3.50 and expire on November 10, 2013 and February 24, 2014. Effective January 1, 2009, we reclassified the fair value of these common stock warrants, from equity to liability status, as if these warrants were treated as a derivative liability since origination.

We determined that the anti-dilution provision built into the preferred shares and warrants issued should be considered for derivative accounting. FASB ASC 815 requires freestanding contracts that are settled in a company's own stock to be designated as an equity instrument, assets or liability. Under the provisions of FASB ASC 815, a contract designated as an asset or liability must be initially recorded and carried at fair value until the contract meets the requirements for classification as equity, until the contract is exercised or until the contract expires. We determined that the anti-dilution provision associated with the November 2007 and February 2008 preferred shares and warrants no longer met the criteria for equity accounting through the revised criteria in FASB ASC 815.

Accordingly, at January 1, 2009, we determined that the warrants and the preferred stock conversion feature should be accounted for as derivative liabilities. The preferred stock conversion feature was determined to have no fair market value at both issuance dates as well as each reporting period until the third quarter of 2010 since management asserts that the likelihood of issuing any new equity at a price that would trigger the anti-dilution effect to be nil. During the third quarter of 2010 we were actively raising capital. With our stock price below \$3.00 a share it was possible that we would sell shares below \$3.00 per share. Since this would require an adjustment to our convertible preferred stock we recorded a derivative liability and expense at September 30, 2010. The derivative liability and expense was revalued at December 31, 2010 and was \$5,840,000; at December 31, 2011 and was \$4,430,000; and at December 31, 2012 and was \$9,200,000. The change in the fair value of the derivative was a gain of \$1,410,000 in 2011 and a loss of \$4,770,000 in 2012. We will continue to reevaluate the derivative liability in future reporting periods and adjust the derivative liability as necessary. The warrants were valued at issuance and each reporting period since using the Black-Scholes model. Both of these derivatives will continue to be marked to market in accordance with FASB ASC 815.

On January 1, 2009 we reclassified the fair value of the warrants from equity to liability as if these warrants were treated as a derivative liability since their issue date. We recorded derivative gain of \$3,580,000 for the year ended December 31, 2011 and \$1,236,000 gain for the year ended December 31, 2012.

#### Series B Cumulative Convertible Preferred Stock

On October 25, 2012, we entered into a Preferred Stock and Warrant Purchase Agreement (the “Purchase Agreement”) with existing investors whereby we agreed to sell 1,000 shares of a newly created series of our preferred stock, designated “Series B Cumulative Convertible Preferred Stock”, par value \$0.01 per share, for an issue price of \$10,000 per share, (the “Series B Preferred Stock”) and agreed to issue warrants to purchase 20,000,000 shares of our common stock at an exercise price of \$0.50 per share, for an aggregate purchase price of \$10,000,000. The financing consisted of \$4,703,000 of new investment and the conversion of approximately \$5,297,000 of outstanding dividends payable on our Series A Preferred Stock. Certain terms of the Series B Preferred Stock are senior in right to the Company’s outstanding Series A Preferred Stock. The Series B financing was approved by the requisite percentage of the holders of the Company’s Series A Preferred Stock and closed on October 25, 2012.

The shares of Series B Preferred Stock issued upon closing are convertible at the option of the holder into shares of our common stock at a conversion price of \$0.50 per share of common stock (the “Conversion Price”). The Conversion Price is not subject to adjustment, except in cases of stock splits, stock dividends or similar transactions.

The Series B Preferred Stock is entitled to a liquidation preference, senior to the liquidation preference of the Series A Preferred Stock, equal to the greater of (i) (A) two times (2x) the Stated Value for the Series B Preferred Stock, plus any accumulated and unpaid dividends (whether or not declared) on the Series B Preferred Stock if such liquidation takes place prior to the fifth anniversary of the original issue date or (B) three times (3x) the Stated Value for the Series B Preferred Stock, plus any accumulated and unpaid dividends (whether or not declared) on the Series B Preferred Stock if such liquidation takes place on or after to the fifth anniversary of the original issue date, or (ii) the cash or other property distributable upon such liquidation with respect to the shares of Common Stock into which such shares of Series B Preferred Stock, including any accrued dividends thereon, could have been converted immediately prior to such payment. “Stated Value” shall mean \$10,000 per share of Series B Preferred Stock, as it may be increased from time to time as set forth in the Certificate of Designations. The Series B Preferred Stock is also entitled to a dividend of 12% per annum, payable quarterly in cash or additional Stated Value, at the election of the majority holders at time of payment.

The Company has the right, but not the obligation, and with the written consent of the majority holders, to force conversion (“Mandatory Conversion”) of all, but not less than all, of the outstanding Series B Preferred Stock into common stock as long as the closing price of our common stock exceeds \$5.00 for at least 20 consecutive trading days immediately prior to the conversion and the average daily trading volume is not less than 200,000 shares per day for at least 20 consecutive trading days immediately prior to such date on which the Company gives notice of such conversion. The Company’s ability to cause a Mandatory Conversion is subject to certain other conditions, including that a registration statement covering the common stock issuable upon such Mandatory Conversion is in effect and able to be used.

The Series B Preferred Stock will vote together with the common stock on an as-if-converted basis. The consent of the Series B Preferred Stock is required for the Company to take certain actions.

The common stock purchase warrants issued are for an aggregate of 20,000,000 shares of our common stock at an exercise price of \$0.50. The warrants can also be exercised on a cashless basis. The warrants will expire six years from the date of issuance.



The warrant exercise price is subject to equitable adjustment for stock splits, dividends, combinations, and reorganizations only.

Liquidated Damages

Pursuant to the terms of an Investor Rights Agreement with the Purchasers of Series A Preferred Stock, we are 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, we accrued \$857,000 in potential liquidated damages as of December 31, 2012 and December 31, 2011. Potential liquidated damages are capped at 10% of each holder's investment. 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 – Series A

Preferred stock dividends of \$3,266,000 were accrued at December 31, 2012, plus interest. Dividends are payable semi-annually in either cash or common stock.

Preferred Stock Dividends – Series B

Preferred stock dividends of \$220,000 were accrued at December 31, 2012, plus interest. Dividends are payable quarterly in either cash or Series B preferred stock.

**NOTE 10 – STOCKHOLDERS' EQUITY**

Warrants

There were warrants to purchase a total of 35,733,943 shares of common stock outstanding at December 31, 2012. All warrants were exercisable at December 31, 2012. The warrants had various exercise prices and terms as follows:

<u>Summary of Warrants</u>	<u>Warrants Outstanding</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
2012 Series B private placement (a)	20,000,000	\$ 0.50	10/24/18
2012 investor relations advisor (b)	30,000	1.17	4/19/14
2011 November private placement (c)	2,144,656	1.67	5/10&30/14
2011 November private placement (c)	2,144,656	2.00	11/10&30/16
2011 November placement agent warrants (c)	36,893	1.67&2.00	11/10&30/16
2011 investor relations advisor (d)	12,500	2.30	4/15/14
2010 December registered direct offering (e)	930,664	3.06	12/14/15
2010 January registered direct offering (f)	1,041,432	3.00	1/26/15
2010 January placement agent warrants (f)	125,109	3.75	1/26/15
2010 investor relations advisor (g)	60,000	2.16	10/1/13
2010 investor relations advisor (h)	55,000	2.63	10/14/13
2009 investor relations advisor (i)	25,000	3.50	11/4/14
2009 business consultant (j)	60,000	2.07	7/23/14
2008 preferred stock offering (k)	499,584	0.50	2/24/14
2008 Somanta accounts payable (l)	246,753	3.50	1/4/14
2008 investor relations advisor (m)	50,000	3.15	1/3/13
2008 investor relations advisor (n)	40,000	3.00	9/1/13
2007 preferred stock offering (o)	3,649,880	0.50	11/10/13
2006 convertible note (p)	3,818,180	1.32	2/16/15
2006 convertible note (p)	386,364	1.32	10/24/15
2006 convertible note (p)	377,272	1.32	12/6/15
Total	<u>35,733,943</u>		

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- a) In connection with a private placement offering on October 25, 2012, warrants to purchase 20,000,000 shares of common stock at \$0.50 per share were issued. All of the warrants are exercisable immediately and expire on October 24, 2018.
- b) During 2012, an investor relations advisor received warrants to purchase 30,000 shares of common stock at an exercise price of \$1.17 per share exercisable at any time until April 19, 2014, for investor relations consulting services rendered in 2012. The expense recorded for the year ended December 31, 2012 was \$10,000.
- c) In connection with a private placement offering on November 10 and 30, 2011, warrants to purchase 2,144,656 shares of common stock at \$1.67 per share were issued. All of the warrants are exercisable immediately and 1,857,156 warrants expire May 10, 2014 and 287,500 warrants expire May 30, 2014.

In connection with a private placement offering on November 10 and 30, 2011, additional warrants to purchase 2,144,656 shares of common stock at \$2.00 per share were issued. All of the warrants are exercisable immediately and 1,857,156 warrants expire November 10, 2016 and 287,500 warrants expire November 30, 2016.

Also in connection with a private placement offering on November 10 and 30, 2011, placement agent warrants to purchase 18,447 shares of common stock at \$1.67 per share were issued. Also in connection with a private placement offering on November 10 and 30, 2011, placement agent warrants to purchase 18,446 shares of common stock at \$2.00 per share were issued. All the placement agent warrants are exercisable immediately and 18,447 warrants expire November 10, 2016 and 18,446 warrants expire November 30, 2016.

- d) During 2011, an investor relations advisor received warrants to purchase 12,500 shares of common stock at an exercise price of \$2.30 per share at any time until April 15, 2014, for investor relations consulting services rendered in 2011. The expense recorded for the year ended December 31, 2011 was \$17,000.
- e) In connection with a registered direct offering on December 14, 2010, warrants to purchase 930,664 shares of common stock at \$3.06 per share were issued. All of the warrants are exercisable immediately and expire December 14, 2015.
- f) In connection with a registered direct offering on January 26, 2010, warrants to purchase 1,041,432 shares of common stock at \$3.00 per share were issued. All of the warrants are exercisable immediately and expire January 26, 2015.

In addition, we issued warrants for placement agent fees to purchase 125,109 shares of our common stock at an exercise price of \$3.75 per share. All of the warrants are exercisable immediately and expire January 26, 2015.

- g) During 2010, an investor relations advisor received warrants to purchase 194,000 shares of common stock at an exercise price of \$2.16 per share for investor relations consulting services rendered in 2010 and 2011. Our common stock did not reach a target price by February 28, 2011 and according to the agreement 134,000 warrants expired and no further expense was recorded. Warrants to purchase 60,000 shares of common stock are exercisable and outstanding at December 31, 2011 and expire October 1, 2013.
- h) During 2010, an investor relations advisor received warrants to purchase 55,000 shares of common stock at an exercise price of \$2.63 per share at any time until October 14, 2013, for investor relations consulting services rendered in 2010.



- i) During 2010, an investor relations advisor received warrants to purchase 25,000 shares of common stock at an exercise price of \$3.50 per share at any time until November 4, 2014, for investor relations consulting services rendered in 2010.
- j) During 2009, a business consultant received warrants to purchase 150,000 shares of common stock at an exercise price of \$2.07 per share at any time until July 23, 2014, for business consulting services rendered in 2009. 60,000 of the warrants were exercisable on December 31, 2011. The remaining 90,000 warrants expired July 23, 2010 because our stock did not reach specified trading prices.
- k) 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 February 24, 2014. 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. The exercise price of \$3.50 was decreased to \$3.00 after the January 2010 placement; to \$2.55 after the December 2010 placement; to \$1.45 after the November 2011 placement; and, to \$0.50 after the October 2012 placement.
- l) In connection with our acquisition of Somanta Pharmaceuticals, Inc. (Somanta) we exchanged for \$1,576,000 due to Somanta vendors, for 538,508 shares of our common stock and warrants to purchase 246,753 shares of common stock at \$3.50. The warrants expire January 4, 2014.
- m) 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 rendered in 2008.
- n) 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.
- o) 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. The exercise price of \$3.50 was decreased to \$3.00 after the January 2010 placement; to \$2.55 after the December 2010 placement; to \$1.45 after the November 2011 placement; and, to \$0.50 after the October 2012 placement.
- p) In connection with the convertible note offerings in 2006, warrants to purchase a total of 4,581,816 shares of common stock at \$1.32 per share were issued. All of the warrants are exercisable immediately and expire six years from date of issue. On February 10, 2012 these warrants were extended an additional three years.

2011 Private Placement Offering – New Common Stock and Warrants

On November 10 and 30, 2011, we completed the sale of 4,289,312 shares of our common stock and two and one half year warrants to purchase 2,144,656 shares of our common stock at an exercise price of \$1.67 per share and five year warrants to purchase 2,144,656 shares of our common stock at an exercise price of \$2.00 per share for an aggregate purchase price of \$6.2 million. Proceeds, net of cash issuance costs from the sale, were \$5.8 million.

In connection with the sale we issued warrants for placement agent fees to purchase 18,447 shares of common stock at \$1.67 per share and 18,446 shares of common stock at \$2.00 per share. All of the warrants are exercisable immediately and expire five years from the date of issue.

2012 Warrant Adjustments

On February 10, 2012, we entered into amendment agreements for 4,581,816 currently outstanding warrants which extended the expiration dates of such warrants to February 16, 2015 for 3,818,180 warrants; to October 24, 2015 for 386,364 warrants; and to December 6, 2015 for 377,272 warrants. The holders of such warrants are SCO Capital Partners LLC, Lake End Capital LLC and Beach Capital LLC. These holders may be deemed to be affiliates of Jeffrey B. Davis and Steven H. Rouhandeh, our Chief Executive Officer and a director, respectively, as well as other un-affiliated warrant holders. The warrants that were amended were for the purchase of an aggregate of 4,581,816 shares of our common stock. In connection with the amendments, the holders of such warrants agreed to waive any damages that they may have incurred relating to the Company's inability to register the shares of common stock issuable upon exercise of the warrants, other than liquidated damages that may have already accrued relating to such inability to register such shares.

**NOTE 11 - STOCK OPTION PLANS**

We account for stock based compensation expense in accordance with FASB ASC 718, *Stock Based Compensation*. We have several stock-based compensation plans under which incentive and non-incentive qualified stock options and restricted shares may be granted to employees, directors and consultants. We measure the cost of the employee/director/consultant services received in exchange for an award of equity instruments based on the grant date fair value of the award.

Our 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 5,000,000 shares of our authorized but unissued common stock were reserved for issuance to employees, consultants, or to non-employee members of the Board or to 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 2012: dividend yield of 0%; volatility of 98%; risk-free interest rate of 0.45%; and expected lives of 5.5 years. The weighted average fair value of options granted was \$0.29 per share during 2012. The assumptions for grants in fiscal 2011 were: dividend yield of 0%; volatility of 117%; risk-free interest rate of 1.42%; and expected lives of 5.6 years. The weighted average fair value of options granted was \$1.87 per share during 2011.

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

	Options	Weighted- average exercise price
Outstanding options at January 1, 2011	1,748,733.00	\$ 2.13
Granted, fair value of \$ 1.87 per share	580,000.00	2.22
Exercised/forfeited	<u>(61,949.00)</u>	1.38
Outstanding options at December 31, 2011	2,266,784.00	2.17
Granted, fair value of \$ 0.29 per share	1,235,000.00	0.39
Expired/forfeited	<u>(838,000.00)</u>	2.14
Outstanding options at December 31, 2012	<u>2,663,784.00</u>	1.36
Exercisable at December 31, 2012	1,797,742.00	1.72

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The intrinsic value of options under this plan related to the outstanding and exercisable options were \$7,000 and \$1,000 at December 31, 2012, respectively. The intrinsic value of options under this plan related to the outstanding and exercisable options were \$324,000 and \$324,000, respectively at December 31, 2011.

The total intrinsic value of options exercised during 2012 was none and during 2011 was none.

Further information regarding options outstanding under the 2005 Equity Incentive Plan at December 31, 2012 is summarized below:

<u>Range of exercise prices</u>	<u>Number of options outstanding</u>	<u>Weighted average</u>		<u>Number of options exercisable</u>	<u>Weighted-average</u>	
		<u>Remaining life in years</u>	<u>Exercise price</u>		<u>Remaining life in years</u>	<u>Exercise price</u>
\$0.23	725,000	10.0	\$ 0.23	106,250	10.0	\$ 0.23
\$0.61 - 0.85	640,000	7.3	\$ 0.63	510,000	6.7	\$ 0.63
\$1.38	220,000	7.0	\$ 1.38	220,000	7.0	\$ 1.38
\$2.27 – 3.15	1,078,784	7.9	\$ 2.54	961,492	7.9	\$ 2.55
	<u>2,663,784</u>			<u>1,797,742</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, 2012, all 450,000 shares were available for grant under the Plan.

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, 2012, there were no additional shares available for grant under the 1995 Stock Awards Plan. A total of 39,500 options were outstanding under this plan at December 31, 2012.

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:

	<u>Options</u>	<u>Weighted-average exercise price</u>
Outstanding options at January 1, 2011	59,500.00	16.80
Expired	(2,000.00)	23.05
Outstanding options at December 31, 2011	57,500.00	16.58
Expired	(18,000.00)	18.14
Outstanding options at December 31, 2012	<u>39,500.00</u>	15.87
Exercisable at December 31, 2012	<u>39,500.00</u>	15.87

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There was no intrinsic value related to outstanding or exercisable options under this plan at December 31, 2012 or 2011.

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2012 is summarized below:

<u>Range of exercise prices</u>	<u>Number of Options outstanding</u>	<u>Weighted average</u>		<u>Number of options exercisable</u>	<u>Weighted-average</u>	
		<u>Remaining life in years</u>	<u>Exercise price</u>		<u>Remaining life in years</u>	<u>Exercise price</u>
\$ 10.10 - 12.40	29,000	2.1	\$ 11.09	29,000	2.1	\$ 11.09
\$ 28.50 - 29.25	10,500	2.0	\$ 29.07	10,500	2.0	\$ 29.07
	<u>39,500</u>			<u>39,500</u>		

**NOTE 12 - INCOME TAXES**

Income tax expense differs from the statutory amounts as follows:

	<u>2012</u>	<u>2011</u>
Income taxes at U.S. statutory rate	\$ (3,581,000)	\$ (861,000)
State taxes	-	17,000
Current year reserve	2,794,000	857,000
Expenses not deductible	787,000	4,000
Total tax expense	<u>\$ -</u>	<u>\$ 17,000</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>2012</u>	<u>2011</u>
<b>Deferred tax assets</b>		
Net operating loss carryforwards	\$ 64,147,000	\$ 63,830,000
General business credit carryforwards	2,450,000	2,439,000
State credits	3,072,000	3,097,000
Property and equipment	57,000	46,000
Stock options	1,531,000	1,480,000
Derivatives	4,007,000	2,018,000
Deferred revenue	899,000	1,221,000
Intangible assets	517,000	415,000
Accrued interest	253,000	253,000
Other	230,000	231,000
Gross deferred tax assets	77,163,000	75,030,000
Valuation allowance	<u>(77,163,000)</u>	<u>(75,030,000)</u>
Net deferred taxes	<u>\$ -</u>	<u>\$ -</u>

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At December 31, 2012, we had approximately \$188,666,000 of net operating loss carryforwards and approximately \$2,450,000 of general business credit carryforwards. These carryforwards expire as follows:

	Net operating loss carryforwards	General business credit carryforwards
2012	\$ -	\$ -
2013	-	-
2014	-	-
2015	-	-
Thereafter	188,666,000	2,450,000
	<u>\$ 188,666,000</u>	<u>\$ 2,450,000</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.

Additionally, we acquired MacroChem Corporation on February 25, 2009 and Somanta Pharmaceuticals, Inc. on January 4, 2008. Both corporations were loss companies at the time of the acquisition. Therefore, the net operating losses related to those acquisitions may be subject to annual limitations as provided by IRC Sec. 382.

We account for uncertain income tax positions in accordance with FASB ASC 740, *Income Taxes*. 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, 2012 and 2011, we did not recognize any uncertain income tax positions or 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.



**Subsidiaries of the Registrant**

MacroChem Corporation, a Delaware company

Virium Pharmaceuticals, Inc., 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 19, 2013, accompanying the consolidated financial statements included in the Annual Report of Access Pharmaceuticals, Inc. and subsidiaries on Form 10-K for the years ended December 31, 2012 and 2011. 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. 333-179603, 333-178415, 333-166453, 333-162687, 333-149633, and 333-135734), Form S-4 (File No. 333-143587), and Form S-8 (File Nos. 333-169067, 333-161642, 333-45646, 333-75136, 333-125796, and 333-114269).

/s/ Whitley Penn LLP

Dallas, Texas  
March 19, 2013

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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 19, 2013

/s/ Jeffrey B. Davis

B. Davis

Jeffrey

Executive Officer

Chief

Executive Officer

Principal

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 19, 2013

/s/ Stephen B. Thompson

Thompson

Stephen B.

Financial Officer

Chief

Financial and Accounting Officer

Principal

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-K for the period ended December 31, 2012 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 19th day of March, 2013.

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

/s/ Stephen B. Thompson  
Stephen B. Thompson  
Chief Financial Officer  
Principal Financial and Accounting Officer

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