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SUBJECT TO COMPLETION, DATED JANUARY 20, 2012

PROSPECTUS

**ACCESS PHARMACEUTICALS, INC.**

8,615,517 Shares of Common Stock

This Prospectus relates to the offer and sale of up to 8,615,517 shares of common stock, \$0.01 par value per share, of Access Pharmaceuticals, Inc. ("Access") by certain stockholders of Access, listed in the Selling Stockholders Table beginning on page 16.

Access is not selling any shares of common stock in this offering and therefore will not receive any of the proceeds from this offering. However, if the warrants are exercised, Access will receive the proceeds from such exercise if payment is made in cash. All costs associated with this registration will be borne by Access.

The shares of common stock are being offered for sale by the selling stockholders at prices established on the OTC Bulletin Board during the term of this offering. On January 18, 2012, the last reported sale price of our common stock was \$1.38 per share. Our common stock is presently listed on the OTC Bulletin Board under the symbol "ACCP". These prices will fluctuate based on the demand for the shares of common stock.

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state law or that an exemption from registration is available.

No underwriter or person has been engaged to facilitate the sale of shares of common stock in this offering. None of the proceeds from the sale of stock by the selling stockholders will be placed in escrow, trust or any similar account.

**These securities are speculative and involve a high degree of risk.**  
**You should purchase securities only if you can afford a complete loss of your investment.**

See "Risk factors" beginning on page 6.

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**These securities have not been approved or disapproved by the Securities and Exchange Commission or any state securities commission nor has the Securities and Exchange Commission or any state securities commission passed upon the accuracy or adequacy of this Prospectus. Any representation to the contrary is a criminal offense.**

THE DATE OF THIS PROSPECTUS IS JANUARY 20, 2012.

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## PROSPECTUS SUMMARY

### Access Pharmaceuticals, Inc.

8,615,517 Shares of Common Stock

## ABOUT THIS PROSPECTUS

This summary highlights certain information appearing elsewhere in this prospectus. For a more complete understanding of this offering, you should read the entire prospectus carefully, including the risk factors and the financial statements. References in this prospectus to “we,” “us,” “our,” “Company” and “Access” refer to Access Pharmaceuticals, Inc. You should read both this prospectus and any prospectus supplement together with additional information described below under the heading "Where You Can Find More Information" on page 66.

## ABOUT ACCESS

### Company Overview

Access Pharmaceuticals, Inc. (together with our subsidiaries, “We”, “Access” or the “Company”) is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one approved product, two products at Phase 2 of clinical development and several products in pre-clinical development. Low priority clinical and pre-clinical programs will be dependent on our ability to enter into collaboration arrangements. Certain of our development programs are dependent upon our ability to secure approved funding for such projects.

- MuGard™ is our approved product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the FDA. We launched MuGard in the United States in the fourth quarter of 2010. We are continuing training of our third-party MuGard representatives on the product, on the oral mucositis condition and on our sales strategy. MuGard prescriptions are growing weekly and we have placed emphasis on our sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake. MuGard has also been launched in Germany, Italy, UK, Greece and the Nordic countries by our European commercial partner, SpePharm. Our China partners have received the acceptance letter from the State Food and Drug Administration of China. We anticipate marketing approval in China in the first quarter of 2012.
- Our lead development candidate for the treatment of cancer is ProLindac™, a nanopolymer DACH-platinum prodrug. We initiated a study of ProLindac combined with Paclitaxel in second line treatment of platinum pretreated advanced ovarian cancer patients in the fourth quarter of 2010. This multi-center study of up to 25 evaluable patients is being conducted in France. We are also currently planning a number of combination trials, looking at combining ProLindac with other cancer agents in solid tumor indications including colorectal and ovarian cancer. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has sales in excess of \$2.0 billion.
- Thiarabine, or 4-thio Ara-C, is a next generation nucleoside analog licensed from Southern Research Institute. Previously named SR9025 and OSI-7836, the compound has been in two Phase 1/2 solid tumor human clinical trials and was shown to have anti-tumor activity. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and have initiated additional Phase 2 clinical trials in adult AML, ALL and other indications.
- CobOral® is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We are currently developing a product for the oral delivery of insulin, and have conducted sponsored development of a product for oral delivery of human growth hormone. We have signed or are in discussion with several companies regarding the sponsored development of CobOral drug delivery formulations of proprietary and non-proprietary actives.



- CobaCyte®-mediated cancer targeted delivery is a preclinical technology which makes use of the fact that cell surface receptors for vitamins such as B12 are often overexpressed by cancer cells. This technology uses nanopolymer constructs to deliver more anti-cancer drug to tumors while protecting normal tissues.

## Products and Product Candidates

We use our drug delivery technologies to develop the following products and product candidates:

### Access Drug Portfolio

<u>Compound</u>	<u>Originator</u>	<u>Technology</u>	<u>Indication</u>	<u>Clinical Stage (1)</u>
MuGard™	Access	Mucoadhesive liquid	Mucositis	Launched U.S. and EU
ProLindac™ (Polymer Platinite, AP5346) (2)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Thiarabine (4-thio Ara-C) (3)	Southern Research Institute	Small molecule	Cancer	Phase 1/2
Oral Insulin	Access	Cobalamin	Diabetes	Pre-clinical
CobOral® Delivery System	Access	Cobalamin	Various	Pre-clinical
CobaCyte®-Targeted Therapeutics	Access	Cobalamin	Anti-tumor	Pre-clinical

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- (1) For more information, see “Government Regulation” for description of clinical stages.
  - (2) Licensed from the School of Pharmacy, The University of London.
  - (3) Licensed from Southern Research Institute of Birmingham, Alabama.

## Recent Developments

On November 30, 2011, we closed the sale of approximately 575,000 shares of our common stock and warrants to purchase 575,000 shares of our common stock for gross proceeds of approximately \$834,000. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$2.00 per whole share exercisable for five years).

On November 17, 2011, we paid \$2.75 million of a secured promissory note. The remaining \$2.75 million of the secured promissory note is due September 13, 2012.

On November 10, 2011, we closed the sale of approximately 3.71 million shares of our common stock and warrants to purchase 3.71 million shares of our common stock for gross proceeds of approximately \$5.39 million. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$2.00 per whole share exercisable for five years).

On November 9, 2011, we announced we entered into an agreement with a pharmaceutical company in the RNAi industry to exploit our CobaCyte and CobOral technology for the delivery of RNAi therapeutics. We will provide the pharmaceutical company with CobOral and CobaCyte siRNA formulation for evaluation of gene knockdown following oral and intravenous administration. Any successful formulation developed will be jointly owned by the Parties and subject to a subsequent full licensing agreement.

## **Other Key Developments**

In various news releases over the past quarter we announced that MuGard has received reimbursement from many networks of leading insurance and pharmacy benefit managers throughout the U.S., including Aetna, Amerigroup, several state Anthem plans, Assurant Health, several Blue Cross Blue Shield state plans, Cigna, Express-Scripts, Harvard Pilgrim, Humana, Keystone, Tricare, United Healthcare, Wellspan Plus. Reimbursement coverage for MuGard is now available with standard pharmacy benefit copayment. Placement in pharmacy benefit plans will assist in driving increased reimbursement coverage in MuGard.

On September 7, 2011, we announced that we contracted with CuraScript, a healthcare subsidiary of Express Scripts, to expand our specialty pharmacy and third party logistics networks for MuGard. We also contracted with CuraScript Specialty Distribution to warehouse and serve as our specialty distributor and wholesaler for specialty pharmacy providers.

On August 5, 2011, we announced that we hired Edelman, the leading full service global public relations firm, to support our media outreach initiatives. Edelman will assist us in implementing a media communications outreach program primarily aimed at introducing MuGard and building awareness of its ability to treat oral mucositis

On July 28, 2011, we announced that we launched our patient reimbursement and support center for our lead product for oral mucositis, MuGard. Referred to as a HUB, the MuGard Patient Reimbursement and Support Center (MuGard PRSC) operated by eMax Health provides a centralized patient referral center that improves patient access to MuGard by enhancing product distribution and facilitating payment for MuGard by insurance carriers.

On July 12, 2011, we announced that we signed an agreement to restructure the outstanding \$5.5 million senior convertible promissory note scheduled to mature this year, that agreement was amended on August 15, 2011. The agreements provide for an extension of 50% of the note (\$2.75 million) until September 13, 2012, and require the payment of \$2.75 million to be paid promptly on the earlier of December 1, 2011 or upon the closing of an equity financing by the Company. If the initial \$2.75 million is not paid prior to December 1, 2011, then the full \$5.5 million plus accrued interest will become due and payable on December 13, 2011. The amendments provided the note holder with a security interest in certain of our assets and required an interest payment on August 15, 2011.

The amended agreement provides for the extension of 50% of the principal amount of the note (\$2.75 million) until September 13, 2012. The restructured agreement provides for the acceleration of payments to the note holder in the event of a corporate licensing or partnering transaction and also provides the note holder with a security interest in certain of our assets.

On June 27, 2011, we announced that RHEI Pharmaceuticals, our MuGard partner in China, has received the acceptance letter from the State Food and Drug Administration (SFDA) of China acknowledging all necessary documentation for MuGard has been submitted and accepted. Together with its marketing partner Jian An, RHEI Pharmaceuticals completed the process required to satisfy all requirements to receive marketing approval in China and its other South East Asian territories. RHEI has advised Access of the next steps the SFDA will take to grant approval in its territories and anticipates receiving marketing approval in the second half of this year.

On May 24, 2011, we announced that we signed an agreement with eMAX Health Systems to expand the distribution network and to further support ongoing third party payer outreach programs for MuGard and advocate for reimbursement among commercial insurance carriers in the United States.

On May 10, 2011, we announced that we have made significant progress with our CobaCyte tumor-targeting technology. Using a new proprietary CobaCyte paclitaxel nanoparticle formulation, named Cobraxane™, our scientists have observed significant tumor growth inhibition in preclinical tumor models.

## **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.



## SUMMARY OF THE OFFERING

This offering relates to the sale of common stock by certain persons who are the selling stockholders who intend to sell up to 8,615,517 shares of common stock, consisting of (1) 4,289,312 shares of our common stock; (2) 2,163,103 shares are issuable to selling stockholders upon exercise of warrants for the purchase of shares of our common stock at \$1.67 per share, including shares issuable to selling stockholders upon the exercise of warrants for the purchase of shares of our common stock at \$1.67 per share received as placement agent fees pursuant to the sale of common stock; and (3) 2,163,102 shares are issuable to selling stockholders upon exercise of warrants for the purchase of shares of our common stock at \$2.00 per share, including shares issuable to selling stockholders upon the exercise of warrants for the purchase of shares of our common stock at \$2.00 per share received as placement agent fees pursuant to the sale of common stock.

Our registration of these shares does not necessarily mean that the selling shareholders will exercise any of these warrants or sell any or all of the shares of our common stock that we are registering.

Common stock offered by Access:	None.
Common stock offered by selling shareholders:	8,535,517 shares, which includes 4,326,205 shares issuable upon exercise of warrants as described above.
Common stock outstanding:	As of January 18, 2012, 23,897,870 shares of our common stock were issued and outstanding.
Preferred stock outstanding:	As of January 18, 2012, there were 2,938.3617 shares of Series A Cumulative Convertible Preferred Stock issued and outstanding convertible into 20,264,551 shares of our common stock.
Offering Price:	To be determined by the prevailing market price for the shares at the time of the sale or in negotiated transactions.
Proceeds to Access:	We will not receive proceeds from the resale of shares by the selling shareholders. We may receive proceeds from the exercise of any outstanding warrants for cash.
Use of proceeds:	We will not receive any of the proceeds from the sale by any selling shareholder of our common stock.
OTC Bulletin Board Symbol:	ACCP:OB

## SUMMARY CONDENSED CONSOLIDATED FINANCIAL INFORMATION

The following summary selected condensed consolidated financial information as of and for the years ended December 31, 2010 and 2009, have been derived from our audited financial statements. The financial information as of and for the nine months ended September 30, 2011 and 2010 is derived from our unaudited condensed consolidated financial statements. The condensed consolidated financial information set forth below should be read in conjunction with “Management's Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and notes thereto included elsewhere in this prospectus.

On February 25, 2009, we closed our acquisition of MacroChem Corporation through the issuance of an aggregate of approximately 2.5 million shares of our common stock. The acquisition was recorded similar to the pooling-of-interest method and the financial information for all periods presented reflects the financial statements of the combined companies in accordance with Financial Accounting Standards Board standards on business combinations for entities under common control.

<b>(in thousands, except per share amounts)</b>	<u>For the Nine Months</u>		<u>For the Year</u>	
	<u>Ended</u>		<u>Ended</u>	
	<u>September 30,</u>	<u>September 30,</u>	<u>December 31,</u>	<u>December 31,</u>
	2011	2010	2010	2009
	(unaudited)	(unaudited)		
<b>Consolidated Statement of Operations:</b>				
Total revenues	\$ 1,342	\$ 334	\$ 481	\$ 352
Loss from operations	(6,186)	(5,879)	(7,757)	(9,676)
Interest and miscellaneous income	1,291	554	2,046	29
Interest and other expense	(760)	(444)	(607)	(539)
Gain (loss) on change in fair value of derivative warrants	3,312	6,384	4,621	(7,154)
Loss on change in fair value of derivative preferred stock	(470)	(10,455)	(5,840)	-
Net loss	(2,813)	(9,840)	(7,537)	(17,340)
Preferred stock dividends	(1,327)	(1,340)	(1,791)	(1,886)
Net loss allocable to common stockholders	\$(4,140)	\$(11,180)	\$(9,328)	\$(19,226)
<b>Common Stock Data:</b>				
Basic and diluted net loss per common share				
Net loss allocable to common stockholders	\$ (0.21)	\$ (0.73)	\$ (0.60)	\$ (1.63)
Weighted average basic and diluted common shares outstanding	19,379	15,337	15,633	11,819

	<u>September 30,</u>		<u>December 31,</u>	
	2011	2010	2010	2009
	(unaudited)	(unaudited)		
<b>Consolidated Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 1,348	\$1,496	\$7,033	\$ 607
Total assets	2,220	2,279	8,771	1,583
Deferred revenue	3,620	4,817	4,729	5,077
Derivative liability warrants	1,775	3,324	5,087	9,708
Derivative liability preferred stock	6,310	10,455	5,840	-
Convertible notes	5,500	5,500	5,500	5,500
Total liabilities	25,687	32,732	29,566	28,572

Total stockholders' deficit	(23,467)	(30,453)	(20,795)	(26,989)
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## RISK FACTORS

*Any investment in our securities involves a high degree of risk. You should carefully consider the risks described below, which we believe represent certain of the material risks to our business, together with the information contained elsewhere in this Prospectus, before you make a decision to invest in our securities. If any of the following events occur, our business, financial condition and operating results may be materially adversely affected. In that event, the trading price of our securities could decline and you could lose all or part of your investment.*

### **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, 2010, 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 \$251.1 million through December 31, 2010. Net losses allocable to common stockholders for the years ended 2010 and 2009 were \$9.3 million and \$19.2 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, 2010 was approximately \$567,000 per month. We project our net cash burn rate from operations for the next twelve months to be approximately \$550,000 per month. 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 2012. We are a party to a \$2.75 million secured promissory note due on September 13, 2012. If we are unable to extend this note we may not have sufficient capital to continue our operations. 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 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, 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.**

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.

**Our ability to successfully commercialize, and market our product candidates could be limited if a number of these existing relationships are terminated.**

Furthermore, our strategy with respect to our polymer platinate program is to enter into a licensing agreement with a pharmaceutical company pursuant to which the further costs of developing a product would be shared with our licensing 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, market introduction and subsequent sales of such products. Moreover, contract manufacturers that we may use must adhere to current Good Manufacturing Practices, as required by the FDA. In this regard, the FDA will not issue a pre-market approval or product and establishment licenses, where applicable, to a manufacturing facility for the products until the manufacturing facility passes a pre-approval plant inspection. If we are unable to obtain or retain third party manufacturing on commercially acceptable terms, we may not be able to commercialize our products as planned. Our potential dependence upon third parties for the manufacture of 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 platinum 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. We generally procure product liability insurance for drug candidates that are undergoing human clinical trials. Product liability insurance for the biotechnology industry is generally expensive, if available at all, and as a result, we may be unable to obtain insurance coverage at acceptable costs or in a sufficient amount in the future, if at all. We may be unable to satisfy any claims for which we may be held liable as a result of the use or misuse of products which we 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 are necessary for our success.**

As a result of our acquisition of MacroChem Corporation, we obtained rights to some product candidates through license agreements with various third party licensors. The main third party licensor is for the License Agreement, dated as of August 8, 2007, by and between Virium Pharmaceuticals, Inc. (a predecessor in interest to Access) and Southern Research Institute.

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

Pursuant to issuing Series A Cumulative Convertible Preferred Stock and warrants, we entered into an Investor Rights Agreement with the purchasers of Series A Cumulative 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 Series A Cumulative 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 Series A Cumulative 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 January 18, 2012, 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.

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.

**Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings.**

Sales of our common stock in the public market following this offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable or at all. Of the 23,897,870 shares of common stock outstanding as of January 18, 2012, 19,601,475 shares are, or will be, freely tradable without restriction, unless held by our "affiliates." Some of these shares may be resold under Rule 144. The sale of the 20,264,551 shares issuable upon conversion of our outstanding preferred stock and 16,065,611 shares issuable upon exercise of outstanding warrants could also lower the market price of our common stock.

**Risks related to our common stock**

**We have a secured promissory note outstanding in the principle amount of \$2,750,000 which is due on September 13, 2012 and which we may be unable to repay at maturity.**

We have a secured promissory note outstanding to a high net worth individual in the principle amount of \$2.75 million which is due and payable by us on September 13, 2012. This secured promissory note accrues interest at the annual rate of 12.0%. We may not have the funds to repay the holder of the secured promissory note at maturity which would result in our defaulting under the note. If this occurs, the holder of the note would have rights senior to those of our stockholders.

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

The issued and outstanding shares of Series A Cumulative 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 \$1.45 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 \$1.45 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.); Lake End Capital LLC; and Ayer Capital Partners Master Fund LP each beneficially owned approximately 48.2%, 9.4%, 6.0% and 5.4%, respectively, of our common stock on an as converted basis as of January 18, 2012. 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.

**The selling stockholders intend to sell their shares of common stock in the market, which sales may cause our stock price to decline.**

The selling stockholders intend to sell in the public market 8,615,517 shares of our common stock being registered in this offering. That means that up to 8,615,517 shares may be sold pursuant to this registration statement. Such sales may cause our stock price to decline. Our officers and directors and our shareholders who are significant shareholders, as defined by the SEC, will continue to be subject to the provisions of various insider trading and rule 144 regulations.

**The price you pay in this offering will fluctuate and may be higher or lower than the prices paid by other people participating in this offering.**

The price in this offering will fluctuate based on the prevailing market price of our common stock on the OTC Bulletin Board. Accordingly, the price you pay in this offering may be higher or lower than the prices paid by other people participating in this offering.

## FORWARD-LOOKING STATEMENTS

This Prospectus 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, and that involve risks and uncertainties. These statements include, without limitation, statements relating to 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, the size of the prospective markets in which we may offer products, 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 terms of future licensing arrangements, our ability to secure additional financing for our operations, our ability to establish new relationships and maintain current relationships, our ability to attract and retain key personnel, our belief that we will not pay any cash dividends in the foreseeable future, our belief that a failure to obtain necessary additional capital in the future will result in our operations being jeopardized, our belief that we will expend substantial funds to conduct research and development programs, preclinical studies and clinical trials of potential products, our belief that we will continue to invest available funds in certificates of deposit, money market funds, government securities and investment grade interest-bearing securities and that we will not invest in derivative financial instruments, our belief that the market for a mucositis product is in excess of \$1 billion, our belief that we have a rich pipeline of products and product candidates, our belief that we will continue to evaluate the most cost-effective methods to advance our programs, 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. We intend the forward-looking statements to be covered by the safe harbor for forward-looking statements in these sections. The forward-looking information is based on various factors and was derived using numerous assumptions.

Forward-looking statements necessarily involve risks and uncertainties, and our actual results could differ materially from those anticipated in the forward-looking statements due to a number of factors, including those set forth above under “Risk Factors” and elsewhere in this Prospectus. The factors set forth above under “Risk Factors” and other cautionary statements made in this Prospectus should be read and understood as being applicable to all related forward-looking statements wherever they appear in this Prospectus. The forward-looking statements contained in this Prospectus represent our judgment as of the date of this Prospectus. We caution readers not to place undue reliance on such statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason, even if new information becomes available or other events occur in the future.

## SELLING STOCKHOLDERS

The following table presents information regarding the selling stockholders. The selling shareholders are the entities who have assisted in or provided financing to us. A description of each selling shareholder's relationship to us and how each selling shareholder acquired the shares to be sold in this offering is detailed in the information immediately following this table.

Selling Stockholder	Shares Beneficially Owned Before Offering (1)	Percentage of Outstanding Shares Beneficially Owned Before Offering	Shares to be Sold in the Offering	Percentage of Outstanding Shares Beneficially Owned After Offering
Ernest W. Andberg (2)	47,050	*	40,000	*
Alan Andalman (3)	46,000	*	40,000	*
Ayer Capital Partners Kestrel Fund, LP (4)	120,128	*	120,128	-
Ayer Capital Partners Master Fund, LP (5)	5,056,880	9.6%	5,056,880	-
Brio Capital LP (6)	360,348	1.5%	206,900	*
Gary L. Clark (7)	50,000	*	50,000	-
Cowen and Company, LLC (8)	30,862	*	30,862	-
Cranshire Capital Master Fund, Ltd (9)	531,944	2.2%	317,244	*
Del Rey Management LP (10)	220,516	*	165,516	*
Margus Ehatamn (11)	46,000	*	40,000	*
Stan Eilers & Carol Eilers (12)	92,000	*	80,000	*
Epworth – Ayer Capital (13)	340,232	1.4%	340,232	-
Freestone Advantage Partners II LP (14)	27,584	*	27,584	*
Gary Freitag (15)	46,000	*	40,000	*
James Hansen (16)	150,000	*	150,000	-
Iroquois Master Fund Ltd (17)	178,294	*	172,412	*
JALAA Equities LP (18)	150,000	*	150,000	-
Steven D. Johnson (19)	70,000	*	70,000	-
Kingsbrook Opportunities Master Fund LP (20)	206,900	*	206,900	-
John Lipman (21)	12,567	*	905	*
William Kane Mahon (22)	77,500	*	70,000	*
Richard Molinsky (23)	50,000	*	50,000	-
Delano R. Nelson (24)	40,000	*	40,000	-
Next View Capital LP (25)	241,176	1.0%	200,000	*
Rockmore Investment Master Fund Ltd (26)	595,097	2.5%	344,828	1.0%
Rodman & Renshaw LLC (27)	198,629	*	4,522	*
Noam Rubinstein (28)	8,114	*	604	*
Scott Strickland & Mary Strickland (29)	117,647	*	100,000	*
venBio Select Fund LLC (30)	500,000	2.1%	500,000	-
<b>Total:</b>	9,611,468		8,615,517	

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\* - less than 1%

(1) Applicable percentage of ownership is based on 23,897,870 shares of common stock outstanding as of January 18,



2012, together with securities exercisable or convertible into shares of common stock within 60 days of January 18, 2012, for each stockholder. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the Commission under the Securities and Exchange Act of 1934, as amended. Shares of common stock issuable pursuant to options, warrants and convertible securities which are exercisable or convertible within 60 days are treated as outstanding for computing the percentage of the person holding such securities but are not treated as outstanding for computing the percentage of any other person. Unless otherwise noted, each person or group identified possesses sole voting and investment power with respect to shares, subject to community property laws where applicable. Shares not outstanding but deemed beneficially owned by virtue of the right of a person or group to acquire them within 60 days are treated as outstanding only for purposes of determining the number of and percent owned by such person or group.

- (2) Ernest W. Andberg is known to beneficially own an aggregate of 20,000 shares of Access' Common Stock and warrants to purchase an aggregate of 27,050 shares of Access' Common Stock.
- (3) Alan Andalman is known to beneficially own an aggregate of 20,000 shares of Access' Common Stock and warrants to purchase an aggregate of 26,000 shares of Access' Common Stock.
- (4) Ayer Capital Partners Kestrel Fund, LP is known to beneficially own an aggregate of 60,064 shares of Access' Common Stock and warrants to purchase an aggregate of 60,064 shares of Access' Common Stock.
- (5) Ayer Capital Partners Master Fund, LP is known to beneficially own an aggregate of 2,528,440 shares of Access' Common Stock and warrants to purchase an aggregate of 2,528,440 shares of Access' Common Stock. Ayer Capital Partners Master Fund has a restriction on exercise of the warrants they own such that their maximum beneficial ownership in us is 9.9%.
- (6) Brio Capital LP is known to beneficially own an aggregate of 103,450 shares of Access' Common Stock, warrants to purchase an aggregate of 153,450 shares of Access' Common Stock and Series A Preferred Stock which may be converted into an aggregate of 103,448 shares of Access' Common Stock.
- (7) Gary L. Clark is known to beneficially own an aggregate of 25,000 shares of Access' Common Stock and warrants to purchase an aggregate of 25,000 shares of Access' Common Stock.
- (8) Cowen and Company, LLC is known to beneficially own warrants to purchase an aggregate of 30,862 shares of Access' Common Stock.
- (9) Cranshire Capital Advisors, LLC ("CCA") is the investment manager of Cranshire Capital Master Fund, Ltd. ("Cranshire Master Fund") and has voting control and investment discretion over securities held by Cranshire Master Fund. Mitchell P. Kopin ("Mr. Kopin"), the president, the sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities held by Cranshire Master Fund.

CCA is also investment manager (i) of Cranshire Capital, L.P. ("Cranshire Capital") and (ii) for managed accounts for Freestone Advantage Partners, LP ("Freestone") and Freestone Advantage Partners II, LP ("Freestone II"), and CCA has voting control and investment discretion over securities held by Cranshire Capital and in the managed accounts for Freestone and Freestone II. Mr. Kopin, the president, the sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA also may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of an additional 214,700 shares of common stock of the issuer, consisting of (i) 25,156 shares of common stock of the issuer held by Cranshire Capital, (ii) 1,667 shares of common stock that are issuable upon conversion of preferred stock held by Cranshire Capital, (iii) 158,529 shares of common stock that are issuable upon exercise of warrants held by Cranshire Capital, (iv) 1,764 shares of common stock of the issuer that are issuable upon exercise of warrants held by Freestone, (v) 13,792 shares of common stock of the issuer held by Freestone II and (vi) 13,792 shares of common stock of the issuer that are issuable upon exercise of warrants held by Freestone II.

- (10) Del Rey Management LP is known to beneficially own an aggregate of 82,758 shares of Access' Common Stock and warrants to purchase an aggregate of 137,758 shares of Access' Common Stock.
- (11) Margus Ehatamn is known to beneficially own an aggregate of 20,000 shares of Access' Common Stock and warrants to purchase an aggregate of 26,000 shares of Access' Common Stock.
- (12) Stan Eilers & Carol Eilers are known to beneficially own an aggregate of 40,000 shares of Access' Common Stock and warrants to purchase an aggregate of 52,000 shares of Access' Common Stock
- (13) Epworth – Ayer Capital is known to beneficially own an aggregate of 170,116 shares of Access' Common Stock and warrants to purchase an aggregate of 170,116 shares of Access' Common Stock.
- (14) Cranshire Capital Advisors, LLC ("CCA") is the investment manager of Freestone Advantage Partners II, LP ("Freestone II") and has voting control and investment discretion over securities held by Freestone II. Mitchell P. Kopin ("Mr. Kopin"), the president, sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities held by Freestone II in such managed account.

CCA is also investment manager (i) of Cranshire Capital, L.P. ("Cranshire Capital"), (ii) of Cranshire Capital Master Fund, Ltd. ("Cranshire Master Fund"), and (iii) for managed accounts for Freestone Advantage Partners, LP ("Freestone"), and CCA has voting control and investment discretion over securities held by Cranshire Capital, Cranshire Capital Master Fund and in such managed account for Freestone. Mr. Kopin, the president, the sole member and the sole member of the Board of Managers of CCA, has voting control over CCA. As a result, each of Mr. Kopin and CCA also may be deemed to have beneficial ownership (as determined under Section 13(d) of the Securities Exchange Act of 1934, as amended) of the securities held by Cranshire Capital, Cranshire Master Fund and Freestone that are described in footnote 9.



- (15) Gary Freitag is known to beneficially own an aggregate of 20,000 shares of Access' Common Stock and warrants to purchase an aggregate of 26,000 shares of Access' Common Stock.
- (16) James Hansen is known to beneficially own an aggregate of 75,000 shares of Access' Common Stock and warrants to purchase an aggregate of 75,000 shares of Access' Common Stock.
- (17) Iroquois Master Fund Ltd. is known to beneficially own an aggregate of 86,206 shares of Access' Common Stock and warrants to purchase an aggregate of 92,088 shares of Access' Common Stock.
- (18) JALAA Equities LP is known to beneficially own an aggregate of 75,000 shares of Access' Common Stock and warrants to purchase an aggregate of 75,000 shares of Access' Common Stock.
- (19) Steven D. Johnson is known to beneficially own an aggregate of 35,000 shares of Access' Common Stock and warrants to purchase an aggregate of 35,000 shares of Access' Common Stock.
- (20) Kingsbrook Opportunities Master Fund LP is known to beneficially own an aggregate of 103,450 shares of Access' Common Stock and warrants to purchase an aggregate of 103,450 shares of Access' Common Stock. Kingsbrook Partners LP ("Kingsbrook Partners") is the investment manager of Kingsbrook Opportunities Master Fund LP ("Kingsbrook Opportunities") and consequently has voting control and investment discretion over securities held by Kingsbrook Opportunities. Kingsbrook Opportunities GB LLC ("Opportunities GP") is the general partner of Kingsbrook Opportunities and may be considered the beneficial owner of any securities deemed to be beneficially owned by Kingsbrook Opportunities. KB GP LLC ("GP LLC") is the general partner of Kingsbrook Partners and may be considered the beneficial owner of any securities deemed to be beneficially owned by Kingsbrook Partners. Ari J. Storch, Adam J. Chill and Scott M. Wallace are the sole managing members of Opportunities GP and GP LLC and as a result may be considered beneficial owners of any securities deemed beneficially owned by Opportunities GP and GP LLC. Each of Kingsbrook Partners, Opportunities GP, GP LLC and Messrs. Storch, Chill and Wallace disclaim beneficial ownership of these securities.
- (21) John Lipman is known to beneficially own warrants to purchase an aggregate of 12,514 shares of Access' Common Stock.
- (22) William Kane Mahon is known to beneficially own an aggregate of 35,000 shares of Access' Common Stock and warrants to purchase an aggregate of 35,000 shares of Access' Common Stock. Mr. Mahon's spouse also owns warrants to purchase an aggregate of 7,500 shares of Access' Common Stock.
- (23) Richard Molinsky is known to beneficially own an aggregate of 25,000 shares of Access' Common Stock and warrants to purchase an aggregate of 25,000 shares of Access' Common Stock.
- (24) Delano R. Nelson is known to beneficially own an aggregate of 20,000 shares of Access' Common Stock and warrants to purchase an aggregate of 20,000 shares of Access' Common Stock.
- (25) Next View Capital, LP is known to beneficially own an aggregate of 100,000 shares of Access' Common Stock and warrants to purchase an aggregate of 141,176 shares of Access' Common Stock.
- (26) Rockmore Investment Master Fund Ltd. is known to beneficially own an aggregate of 227,586 shares of Access' Common Stock and warrants to purchase an aggregate of 367,511 shares of Access' Common Stock. Rockmore Capital, LLC ("Rockmore Capital") and Rockmore Partners, LLC ("Rockmore Partners"), each a limited liability company formed under the laws of the State of Delaware, serve as the investment manager and general partner, respectively, to Rockmore (US) LP, a Delaware limited partnership, which invests all of its assets through Rockmore Investment Master Fund Ltd., an exempted company formed under the laws of Bermuda ("Rockmore Master Fund"). By reason of such relationships, Rockmore Capital and Rockmore Partners may be deemed to share dispositive power over shares of our common stock owned by Rockmore Master Fund. Rockmore Capital and Rockmore Partners disclaim beneficial ownership of such shares of our common stock. Rockmore Partners has delegated authority to Rockmore Capital regarding portfolio management decisions with respect to the shares of common stock owned by Rockmore Master Fund and, as of November 30, 2011, Mr. Bruce T. Bernstein and Mr. Brian Daly, as officers of Rockmore Capital, are responsible for the portfolio management decisions of the shares of common stock owned by Rockmore Master Fund. By reason of such authority, Messrs. Bernstein and Daly may be deemed to share dispositive power over the shares of our common stock owned by Rockmore Master Fund. Messrs. Bernstein and Daly disclaim beneficial ownership of such shares of our common stock and neither of such persons has any legal right to maintain such authority. No other person has sole or shared voting or dispositive power with respect to the shares of our common stock as those terms are used for purposes under Regulation 13D-G of the Securities Exchange Act of 1934, as amended. No person or "group" (as that term is used in Section 13(d) of the Securities Act of 1934, as amended, or the SEC's Regulation 13D-G) controls Rockmore Master Fund. }
- (27) Rodman & Renshaw LLC is known to beneficially own warrants to purchase an aggregate of 198,368 shares of Access' Common Stock.
- (28) Noam Rubinstein is known to beneficially own warrants to purchase an aggregate of 8,078 shares of Access' Common Stock.
- (29) Scott Strickland & Mary Strickland are known to beneficially own an aggregate of 50,000 shares of Access'

Common Stock and warrants to purchase an aggregate of 67,647 shares of Access' Common Stock.  
(30) venBio Select Fund LLC is known to beneficially own an aggregate of 250,000 shares of Access' Common Stock and warrants to purchase an aggregate of 250,000 shares of Access' Common Stock.

Each Selling Stockholder acquired the shares sold in this offering under the Securities Purchase Agreement dated November 1, 2011. The shares were acquired by the Selling Stockholders on the closing dates of November 10, 2011 and November 30, 2011.

On November 10, 2011, we closed the sale of approximately 3.71 million shares of our common stock and warrants to purchase 3.71 million shares of our common stock for gross proceeds of approximately \$5.39 million. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$2.00 per whole share exercisable for five years).

On November 30, 2011, we closed the sale of approximately 575,000 shares of our common stock and warrants to purchase 575,000 shares of our common stock for gross proceeds of approximately \$834,000. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$2.00 per whole share exercisable for five years).

## USE OF PROCEEDS

We will not receive any proceeds from the sale of shares by the selling stockholders. We will receive proceeds from the exercise of warrants if payment of the exercise price is made in cash. All such proceeds will be used for general corporate purposes.

## PLAN OF DISTRIBUTION

The selling stockholders may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved. Any profits on the resale of shares of common stock by a broker-dealer acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. Discounts, concessions, commissions and similar selling expenses, if any, attributable to the sale of shares will be borne by a selling stockholder. The selling stockholders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares if liabilities are imposed on that person under the Securities Act.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus and may sell the shares of common stock from time to time under this prospectus after we have filed a supplement to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933 supplementing or amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares of common stock may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares of common stock purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We are required to pay all fees and expenses incident to the registration of the shares of common stock. We have agreed to indemnify the selling stockholders against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The selling stockholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their shares of common stock, nor is there an underwriter or coordinating broker acting in connection with a proposed sale of shares of common stock by any selling stockholder. If we are notified by any selling stockholder that any material arrangement has been entered into with a broker-dealer for the sale of shares of common stock, if required, we will file a supplement to this prospectus. If the selling stockholders use this prospectus for any sale of the shares of common stock, they will be subject to the prospectus delivery requirements of the Securities Act.

The anti-manipulation rules of Regulation M under the Securities Exchange Act of 1934 may apply to sales of our common stock and activities of the selling stockholders.

## 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 Prospectus.

### OVERVIEW

Access Pharmaceuticals, Inc. (together with our subsidiaries, "We", "Access" or the "Company") is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one approved product, two products at Phase 2 of clinical development and several products in pre-clinical development. Low priority clinical and pre-clinical programs will be dependent on our ability to enter into collaboration arrangements. Certain of our development programs are dependent upon our ability to secure approved funding for such projects.

- MuGard™ is our approved product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the FDA. We launched MuGard in the United States in the fourth quarter of 2010. We are continuing training of our third-party MuGard representatives on the product, on the oral mucositis condition and on our sales strategy. MuGard prescriptions are growing weekly and we have placed emphasis on our sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake. MuGard has also been launched in Germany, Italy, UK, Greece and the Nordic countries by our European commercial partner, SpePharm. Our China partners have received the acceptance letter from the State Food and Drug Administration of China. We anticipate marketing approval in China in the first quarter of 2012.
- Our lead development candidate for the treatment of cancer is ProLindac™, a nanopolymer DACH-platinum prodrug. We initiated a study of ProLindac combined with Paclitaxel in second line treatment of platinum pretreated advanced ovarian cancer patients in the fourth quarter of 2010. This multi-center study of up to 25 evaluable patients is being conducted in France. We are also currently planning a number of combination trials, looking at combining ProLindac with other cancer agents in solid tumor indications including colorectal and ovarian cancer. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has sales in excess of \$2.0 billion.
- Thiarabine, or 4-thio Ara-C, is a next generation nucleoside analog licensed from Southern Research Institute. Previously named SR9025 and OSI-7836, the compound has been in two Phase 1/2 solid tumor human clinical trials and was shown to have anti-tumor activity. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and have initiated additional Phase 2 clinical trials in adult AML, ALL and other indications.
- CobOral® is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We are currently developing a product for the oral delivery of insulin, and have conducted sponsored development of a product for oral delivery of human growth hormone. We have signed or are in discussion with several companies regarding the sponsored development of CobOral drug delivery formulations of proprietary and non-proprietary actives.
- CobaCyte®-mediated cancer targeted delivery is a preclinical technology which makes use of the fact that cell surface receptors for vitamins such as B12 are often overexpressed by cancer cells. This technology uses nanopolymer constructs to deliver more anti-cancer drug to tumors while protecting normal tissues.



## Products and Product Candidates

We use our drug delivery technologies to develop the following products and product candidates:

### Access Drug Portfolio

Compound	Originator	Technology	Indication	Clinical Stage (1)
MuGard™	Access	Mucoadhesive liquid	Mucositis	Launched U.S. and EU
ProLindac™ (Polymer Platinate, AP5346) (2)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Thiarabine (4-thio Ara-C) (3)	Southern Research Institute	Small molecule	Cancer	Phase 1/2
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.

(3) Licensed from Southern Research Institute of Birmingham, Alabama.

### Recent Events

On November 30, 2011, we closed the sale of approximately 575,000 shares of our common stock and warrants to purchase 575,000 shares of our common stock for gross proceeds of approximately \$834,000. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$2.00 per whole share exercisable for five years).

On November 17, 2011, we paid \$2.75 million of a secured promissory note. The remaining \$2.75 million of the secured promissory note is due September 13, 2012.

On November 10, 2011, we closed the sale of approximately 3.71 million shares of our common stock and warrants to purchase 3.71 million shares of our common stock for gross proceeds of approximately \$5.39 million. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$2.00 per whole share exercisable for five years).

On November 9, 2011, we announced we entered into an agreement with a pharmaceutical company in the RNAi industry to exploit our CobaCyte and CobOral technology for the delivery of RNAi therapeutics. We will provide the pharmaceutical company with CobOral and CobaCyte siRNA formulation for evaluation of gene knockdown following oral and intravenous administration. Any successful formulation developed will be jointly owned by the Parties and subject to a subsequent full licensing agreement.

### Other Key Developments

In various news releases over the past quarter we announced that MuGard has received reimbursement from many networks of leading insurance and pharmacy benefit managers throughout the U.S., including Aetna, Amerigroup, several

state Anthem plans, Assurant Health, several Blue Cross Blue Shield state plans, Cigna, Express-Scripts, Harvard Pilgrim, Humana, Keystone, Tricare, United Healthcare, Wellspan Plus. Reimbursement coverage for MuGard is now available with standard pharmacy benefit copayment. Placement in pharmacy benefit plans will assist in driving increased reimbursement coverage in MuGard.

On September 7, 2011, we announced that we contracted with CuraScript, a healthcare subsidiary of Express Scripts, to expand our specialty pharmacy and third party logistics networks for MuGard. We also contracted with CuraScript Specialty Distribution to warehouse and serve as our specialty distributor and wholesaler for specialty pharmacy providers.

On August 5, 2011, we announced that we hired Edelman, the leading full service global public relations firm, to support our media outreach initiatives. Edelman will assist us in implementing a media communications outreach program primarily aimed at introducing MuGard and building awareness of its ability to treat oral mucositis

On July 28, 2011, we announced that we launched our patient reimbursement and support center for our lead product for oral mucositis, MuGard. Referred to as a HUB, the MuGard Patient Reimbursement and Support Center (MuGard PRSC) operated by eMax Health provides a centralized patient referral center that improves patient access to MuGard by enhancing product distribution and facilitating payment for MuGard by insurance carriers.

On July 12, 2011, we announced that we signed an agreement to restructure the outstanding \$5.5 million senior convertible promissory note scheduled to mature this year, that agreement was amended on August 15, 2011. The agreements provide for an extension of 50% of the note (\$2.75 million) until September 13, 2012, and require the payment of \$2.75 million to be paid promptly on the earlier of December 1, 2011 or upon the closing of an equity financing by the Company. If the initial \$2.75 million is not paid prior to December 1, 2011, then the full \$5.5 million plus accrued interest will become due and payable on December 13, 2011. The amendments provided the note holder with a security interest in certain of our assets and required an interest payment on August 15, 2011.

The amended agreement provides for the extension of 50% of the principal amount of the note (\$2.75 million) until September 13, 2012. The restructured agreement provides for the acceleration of payments to the note holder in the event of a corporate licensing or partnering transaction and also provides the note holder with a security interest in certain of our assets.

On June 27, 2011, we announced that RHEI Pharmaceuticals, our MuGard partner in China, has received the acceptance letter from the State Food and Drug Administration (SFDA) of China acknowledging all necessary documentation for MuGard has been submitted and accepted. Together with its marketing partner Jian An, RHEI Pharmaceuticals completed the process required to satisfy all requirements to receive marketing approval in China and its other South East Asian territories. RHEI has advised Access of the next steps the SFDA will take to grant approval in its territories and anticipates receiving marketing approval in the second half of this year.

On May 24, 2011, we announced that we signed an agreement with eMAX Health Systems to expand the distribution network and to further support ongoing third party payer outreach programs for MuGard and advocate for reimbursement among commercial insurance carriers in the United States.

On May 10, 2011, we announced that have made significant progress with our CobaCyte tumor-targeting technology. Using a new proprietary CobaCyte paclitaxel nanoparticle formulation, named Cobraxane™, our scientists have observed significant tumor growth inhibition in preclinical tumor models.

On December 10, 2010, we announced that we entered into definitive agreements for the sale of our common stock at a price of \$2.55 per share. We completed the sale of 3,102,000 shares of our common stock at \$2.55 per share and warrants to purchase 931,000 shares of our common stock at an exercise price of \$3.06 per share for an aggregate purchase price of \$7.9 million. Proceeds, net of cash issuance costs from the sale, were \$7.3 million.

On December 8, 2010, we announced that we entered into an agreement with a major global pharmaceutical company to test our oral insulin formulation based on our proprietary vitamin B-12-based CobOral Drug Delivery Technology. We will provide CobOral insulin to the pharmaceutical company.

On November 3, 2010, we announced that we have commenced a Phase 2 combination trial for our second generation DACH-platinum cancer drug, ProLindac, in platinum-sensitive ovarian-cancer patients. This trial is an open-label, Phase 2 study of ProLindac given intravenously with paclitaxel. The combination trial will be conducted in up to eight European participating centers.

On November 1, 2010, we announced that we have been awarded \$1.5 million in government grants. Under the recently enacted Patient Protection and Affordable Care Act, cash grants were awarded to Qualifying Therapeutic Discovery Projects that showed significant potential in producing new and cost-saving therapies, support job growth and increase U.S. competitiveness. Grants were awarded through a competitive application process, and seven out of eight of our applications were awarded.

On October 27, 2010, we announced that we have entered into a pre-licensing feasibility agreement with a biopharmaceutical company to develop an oral formulation of an undisclosed prostate cancer compound utilizing its proprietary vitamin B-12-based CobOral Drug Delivery Technology. We will develop CobOral formulations for testing by the biopharma company. Though the terms of the agreement have not been disclosed, we have indicated that any successful formulation developed will be jointly owned by the parties and subject to a subsequent full licensing agreement.

On October 20, 2010, we announced that we have submitted additional patent applications, covering our Cobalamin-mediated oral drug delivery technology formulations of many global top-100 injectable drugs, as a result of the growing interest surrounding our proprietary oral delivery technology. The patents cover oral formulations of leading injectables, like bevacizumab (Avastin®), trastuzumab (Herceptin®), adalimumab (Humira®), etanercept (Enbrel®), insulin glargine (Lantus®), and many others. In addition, we rebranded our Cobalamin-mediated oral drug delivery technology as CobOral® delivery technology.

On September 29, 2010, we announced that we have made significant progress with our proprietary Cobalamin-targeted drug-delivery program for siRNA therapies. As a result of the continued advancements made with our Cobalamin program, we rebranded the targeted-drug delivery technology as CobaCyte; and submitted additional patent applications for its improved CobaCyte formulations, including siRNA compositions.

On September 21, 2010, we announced we signed a supply agreement for MuGard with RHEI Pharmaceuticals, Inc. (“RHEI”), a specialty pharmaceutical company focused on bringing proprietary medicines to the China market. Under the agreement we are required to ensure manufacturing capacity of up to a minimum of \$30 million of product in the licensed territories. Coinciding with the signing of the above agreement, we also approved a sub-license agreement between RHEI Pharmaceuticals and Jian An Pharmaceuticals (“Jian An”) Limited in Shenzhen, China in an effort to leverage Jian An’s extensive sales, marketing and regulatory infrastructure for the launch of MuGard in China and Taiwan.

On August 2, 2010, we announced we initiated a Phase 1/2 dose-escalating study of our proprietary, anti-cancer drug, Thiarabine, a nucleoside analogue for patients with hematologic malignancies (cancers of the blood). The primary objective of the study is to determine the maximum tolerated dose (MTD) in two different dosing schedules with various leukemias and lymphomas and recommended Phase II dose. The program is being led by Hagop Kantarjian, M.D., Chair of the Department of Leukemia at The University of Texas MD Anderson Cancer Center in Houston, Texas.

On July 20, 2010, we announced we had signed an exclusive specialty distribution agreement with BioScrip, Inc. for MuGard. The agreement aligns us with comprehensive access to BioScrip’s nationwide distribution platform and the ability to leverage their extensive physician relationships, 110 BioScrip specialty pharmacies, mail distribution capability and diversified payor network.

On July 15, 2010, we announced that we had entered into a pre-licensing feasibility agreement with a leading biotechnology company to develop an oral formulation of its currently-marketed, proprietary injectable drugs. We will utilize our proprietary CobOral Drug Delivery Technology to develop oral formulation of the drug for pre-clinical testing.

On April 13, 2010, we announced that we had completed our first commercial scale production run of MuGard in North America at Accupac, Inc. manufacturing facilities.

On March 30, 2010, we announced that we signed a collaborative development agreement with bioRASI, LLC to facilitate clinical development for our CobOral based oral insulin and CobaCyte based products.

On March 11, 2010, we announced that we had received reports of significant bioavailability of orally delivered insulin in two independently-conducted animal studies with our CobOral Drug Delivery Technology.

On January 22, 2010, we announced the sale of approximately 2.10 million shares of our common stock and warrants to purchase approximately 1.04 million shares of our common stock for gross proceeds of approximately \$6.3 million. We sold these shares and warrants as a combined unit for \$3.00 per unit (each unit consisting of one share and a warrant to purchase 0.5 shares of common stock). The exercise price of the warrants is \$3.00 per share. Proceeds, net of cash issuance costs from the sale, were \$5.8 million.

On January 7, 2010, we announced that we completed enrollment and evaluation of the last additional cohort of patients in the ongoing clinical study of ProLindac as a monotherapy in ovarian cancer patients who received at least two prior platinum based treatment regimens. The additional cohort of 8 patients received the ProLindac batch made by an improved scalable process, which will be used on a larger scale for future clinical and commercial supplies. None of the 8 patients experienced any acute significant adverse events, while treatment had the same beneficial pharmacodynamic effect seen in the first 26 patients treated with the former ProLindac production batch; clinically relevant sustained biomarker decrease (responses by Rustin's criteria) and disease stabilization were seen in several patients. The overall results of our Phase 1/2 exploratory single agent ProLindac study have helped define multiple safe dosing regimens, while the level of patient cohort accrued in the study antitumor activity was as expected in this very heavily pretreated patient cohort.

## **Results of Operations**

### **Comparison of Nine Months Ended September 30, 2011 with the Nine Months Ended September 30, 2010**

Our licensing revenue for the first nine months of 2011 was \$1,110,000 as compared to \$281,000 for 2010. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. In the third quarter 2011, we regained licenses from our former Korean partner for ProLindac and MuGard and recognized all of the previously received license fees (\$849,000) that were recorded in deferred revenue.

Sponsored research and development revenues were \$30,000 for the first nine months of 2011 with no revenues for the same period of 2010. The revenues in 2011 are for research collaborations on our CobOral and CobaCyte projects.

We recorded royalty revenue for MuGard in Europe of \$64,000 for the first nine months of 2011 as compared to \$53,000 for 2010, an increase of \$11,000.

Product sales of MuGard in the United States totaled \$138,000 for the first nine months of 2011 with no revenues for the same period of 2010. Our first sales were recorded in the fourth quarter of 2010.

Total research and development spending for the first nine months of 2011 was \$3,243,000, as compared to \$2,718,000 for 2010, an increase of \$525,000. The increase in expenses was primarily due to:

- increased clinical development with trials for ProLindac, MuGard and Thiarabine (\$700,000);
- increased salary and related costs due to new employees (\$238,000);
- other net increases in research spending (\$87,000).
- decreased stock compensation expense for lower expense of option grants for research and development employees (\$239,000);
- lower external development expenses for ProLindac (\$145,000). The product was made in 2010 and is used in the clinical trials ongoing this year; and
- decreased internal lab costs (\$116,000).

Product costs for MuGard in the United States were \$812,000 for the first nine months of 2011 with no product costs for the same period in 2010. MuGard was launched in the fourth quarter of 2010.

Total general and administrative expenses were \$3,297,000 for the first quarter of 2011, a decrease of \$19,000 compared to the same period in 2010 of \$3,316,000. The decrease in expenses was due primarily to the following:

- decreased general business consulting expenses due to the higher use of outside consultants in 2010 (\$305,000) versus the same period in 2011;
- decreased patent and license fees (\$96,000);
- decreased net other general and administrative expenses (\$3,000);
- increased stock compensation expense due to higher expense of option grants for general and administrative employees and directors (\$169,000);
- increased salary and related costs (\$156,000); and
- increased rent expenses (\$98,000) due to additional office space.

Depreciation and amortization was \$176,000 for the first nine months of 2011 as compared to \$179,000 for 2010.

Total operating expenses for the first nine months of 2011 were \$7,528,000 as compared to total operating expenses of \$6,213,000 for 2010, an increase of \$1,315,000 for the reasons listed above.

Interest and miscellaneous income was \$1,291,000 for the first nine months of 2011 as compared to \$554,000 for 2010, an increase of \$737,000. Miscellaneous income was \$738,000 higher in 2011 due to negotiated payables and write-off of other accounts payable. Interest income is comparable to the same period in 2010.

Interest and other expense was \$760,000 for the first nine months of 2011 as compared to \$444,000 in 2010, an increase of \$316,000. The increase in interest and other expense was due to additional interest that was accrued on the long-term notes due to an increase in the interest rate of the note.

We recorded a gain related to warrants classified as derivative liabilities of \$3,312,000 for the first nine months of 2011 as compared to \$6,384,000 for the same period of 2010. A derivative for warrants was recorded in the fourth quarter of 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 \$470,000 for the first nine months of 2011 and \$10,455,000 for 2010. The derivative was recorded for the first time in the third quarter of 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 \$1,327,000 were accrued for the first nine months of 2011 and \$1,340,000 for 2010, a decrease of \$13,000. The decrease is due to some preferred shareholders converting their ownership to common stock. Dividends are due semi-annually in either cash or common stock.

Net loss allocable to common stockholders for the first nine months of 2011 was \$4,140,000, or a \$0.21 basic and diluted loss per common share, compared with net loss of \$11,180,000, or a \$0.73 basic and diluted loss per common share for the same period in 2010, a decreased loss of \$7,040,000.

### **Comparison of Years Ended December 31, 2010 and 2009**

Our licensing revenue for the year ended December 31, 2010 was \$347,000 as compared to \$315,000 for the same period of 2009, an increase of \$32,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

Sponsored research and development revenues were \$58,000 for the year ended December 31, 2010 with no revenues for the same period of 2009. The revenues in 2010 are for research collaborations on our CobOral and CobaCyte projects.

We recorded royalty revenue for MuGard of \$76,000 for the year ended December 31, 2010 and \$37,000 for the same period of 2009, an increase of \$39,000. Royalties for MuGard were first recorded in the third quarter of 2009.

Total research and development spending for the year ended December 31, 2010 was \$3,349,000, as compared to \$2,657,000 for the same period in 2009, an increase of \$692,000. The increase in expenses was primarily due to:

- increased salary and related costs due to existing employees paid at full salary for the full year of 2010 while employees were paid at a reduced salary for seven months of 2009 plus the addition of a new employee (\$499,000);
- increased stock compensation expense due to additional option grants for research and development employees (\$297,000);
- increased clinical development with the planned starts in trials for MuGard, ProLindac and Thiarabine (\$242,000); and
- other net increases in research spending (\$1,000);
- offset by decreased development costs (\$235,000); and
- offset by decreased scientific consulting expenses (\$112,000).

Product costs, for the launch of MuGard in the United States, were \$140,000 for the twelve months ended December 31, 2010. MuGard was launched in the fourth quarter of 2010.

Total general and administrative expenses were \$4,511,000 for the year ended December 31, 2010, a decrease of \$2,601,000 compared to the same period in 2009 of \$7,112,000. The decrease in expenses was due primarily to the following:

- lower general business consulting expenses due to reduction in use of outside consultants (\$1,921,000);
- lower potential liquidated damages under an investor rights agreement with certain investors (\$182,000);
- lower stock compensation expense due to fewer option grants for general and administrative employees (\$92,000);
- lower patent and license fees (\$222,000);
- lower costs from MacroChem (\$180,000); and
- other net decreases in other general and administrative expenses (\$4,000).

Depreciation and amortization was \$238,000 for the year ended December 31, 2010, as compared to \$259,000 for the same period of 2009, a decrease of \$21,000. This decrease was primarily due to assets becoming fully depreciated.

Total operating expenses for the year ended December 31, 2010, were \$8,238,000 as compared to total operating expenses of \$10,028,000 for same period in 2009, a decrease of \$1,790,000 for the reasons listed above.

Interest and miscellaneous income was \$2,046,000 for the year ended December 31, 2010, as compared to \$29,000 for the same period in 2009, an increase of \$2,017,000. Miscellaneous income is \$2,013,000 higher in 2010 as compared to the same period in 2009 due to \$1,479,000 in grants from the Qualifying Therapeutic Discovery Project Grants from the United States and due to \$534,000 in negotiated payables, write-off of other accounts payable and cash received for other one-time items. Interest income is \$4,000 higher in 2010 as compared to the same period in 2009.

Interest and other expense was \$607,000 for the year ended December 31, 2010, as compared to \$539,000 in the same period of 2009, an increase of \$68,000. The increase in interest and other expense was due to the interest that was accrued on the previous unpaid portion of the long-term notes and dividends.

We recorded a derivative gain related to warrants classified as liabilities of \$4,621,000 for the year ended December 31, 2010 as compared to a derivative loss of \$7,154,000 for the same period of 2009. A derivative for warrants was first recorded in the fourth quarter of 2009 when the fair value of the warrants, that were issued with our Series A Convertible Preferred Stock, were reclassified from equity to a liability per the requirements of new accounting guidance as a result of the repricing feature.

We recorded a derivative loss for the liability related to preferred stock of \$5,840,000 for the year ended December 31, 2010. The derivative was recorded 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 \$1,791,000 were accrued for the year ended December 31, 2010 and \$1,886,000 for the same period of 2009, a decrease of \$95,000. The decrease is due to some preferred shareholders converting their ownership to common stock. Dividends are paid semi-annually in either cash or common stock.

Net loss allocable to common stockholders for the year ended December 31, 2010, was \$9,328,000, or a \$0.60 basic and diluted loss per common share, compared with a loss of \$19,226,000, or a \$1.63 basic and diluted loss per common share for the same period in 2009, a decreased loss of \$9,898,000.

## **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. Royalty revenues and product sales provided limited funding for operations during the nine months ended September 30, 2011. As of November 11, 2011, our cash and cash equivalents were \$5,813,000 and our net cash burn rate for the nine months ended September 30, 2011, was approximately \$697,000 per month. As of September 30, 2011, our working capital deficit was \$12,581,000. Our working capital deficit at September 30, 2011 represented an increase of \$6,445,000 as compared to our working capital deficit as of December 31, 2010 of \$6,136,000. The increase in the working capital deficit at September 30, 2011 reflects nine months of net operating costs. As of September 30, 2011, we had one secured promissory note outstanding in the principal amount of \$5.5 million. One half of the note (\$2.75 million) was paid November 17, 2011, five days after the closing of our equity financing and the remaining \$2.75 million under the secured promissory note is due on September 13, 2012.

As of January 18, 2012, 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 September 30, 2011 of \$255,275,000. 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 2012. 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 convert, repay or restructure our outstanding convertible note and debentures;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- successful regulatory filings.

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

(in thousands)	Twelve Months		Inception To
	ended		
	December 31,		Date (1)
<u>Project</u>	<u>2010</u>	<u>2009</u>	
Polymer Platinate (ProLindac™)	\$ 2,697	\$ 2,507	\$ 30,823
Mucoadhesive Liquid Technology			
(MLT)	329	107	1,947
Others (2)	323	43	5,760
Total	<u>\$ 3,349</u>	<u>\$ 2,657</u>	<u>\$ 38,530</u>

- (1) Cumulative spending from inception of the Company or project through December 31, 2010.
- (2) Includes: CobOral, CobaCyte, Thiarabine 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.

### **Climate Change**

We do not believe there is anything unique to our business which would result in climate change regulations having a disproportional affect 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 United States of America requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reported period. In applying our accounting principles, we must often make individual estimates and assumptions regarding expected outcomes or uncertainties. As you might expect, the actual results or outcomes are often different than the estimated or assumed amounts. These differences are usually minor and are included in our consolidated financial statements as soon as they are known. Our estimates, judgments and assumptions are continually evaluated based on available information and experience. Because of the use of estimates inherent in the financial reporting process, actual results could differ from those estimates.

#### *Asset Impairment*

Our intangible assets at December 31, 2010 consisted primarily of patents acquired in acquisitions and licenses which were recorded at fair value on the acquisition date. We perform an impairment test when indications of impairment exist. At December 31, 2010 and for the year then ended, management believes no impairment of our intangible assets exists.

#### *Revenues*

Our revenues are generated from licensing, research and development agreements and royalties. 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.

#### *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.

Stock-based compensation expense recognized for the years ended December 31, 2010 and 2009 was approximately \$1,015,000 and \$811,000, respectively.

#### *Recent Accounting Pronouncements*

In April 2010, the Financial Accounting Standards Board (FASB) issued ASU 2010-17 (ASU 2010-17), "Revenue Recognition-Milestone Method (Topic 605): Milestone Method of Revenue Recognition." The amendments in this Update are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. If a vendor elects early adoption and the period of adoption is not the beginning of the entity's fiscal year, the entity should apply the amendments retrospectively from the beginning of the year of adoption. We adopted this standard effective January 1, 2011. We do not expect the provisions of ASU 2010-17 to have a material effect on the financial position, results of operations or cash flows of us.

In December 2010, the FASB issued ASU 2010-27, *Fees Paid to the Federal Government by Pharmaceutical Manufacturers*. ASU 2010-27 specifies that the liability for our portion of the annual fee on the pharmaceutical manufacturing industry should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. ASU 2010-27 is effective for calendar years beginning after December 31, 2010, when the fee initially becomes effective. ASU 2010-27 will not impact our consolidated financial position, results of operations or cash flows.

#### **Off-Balance Sheet Transactions**

None

## DESCRIPTION OF BUSINESS

### Business

Access Pharmaceuticals, Inc. (together with our subsidiaries, “We”, “Access” or the “Company”) is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one approved product, two products at Phase 2 of clinical development and several products in pre-clinical development. Low priority clinical and pre-clinical programs will be dependent on our ability to enter into collaboration arrangements. Certain of our development programs are dependent upon our ability to secure approved funding for such projects.

- MuGard™ is our approved product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the 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 weekly and we have placed emphasis on our sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake. MuGard has also been launched in Germany, Italy, UK, Greece and the Nordic countries by our European commercial partner, SpePharm. Our China partners have received the acceptance letter from the State Food and Drug Administration of China. We anticipate marketing approval in China in the first quarter of 2012.
- Our lead development candidate for the treatment of cancer is ProLindac™, a nanopolymer DACH-platinum prodrug. We initiated a study of ProLindac combined with Paclitaxel in second line treatment of platinum pretreated advanced ovarian cancer patients in the fourth quarter of 2010. This multi-center study of up to 25 evaluable patients is being conducted in France. We are also currently planning a number of combination trials, looking at combining ProLindac with other cancer agents in solid tumor indications including cholangiocarcinoma, colorectal and ovarian cancer. 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.
- Thiarabine, or 4-thio Ara-C, is a next generation nucleoside analog licensed from Southern Research Institute. Previously named SR9025 and OSI-7836, the compound has been in two Phase 1/2 solid tumor human clinical trials and was shown to have anti-tumor activity. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and have initiated additional Phase 2 clinical trials in adult AML, ALL and other indications.
- CobOral® is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We are currently developing a product for the oral delivery of insulin, and have conducted sponsored development of a product for oral delivery of human growth hormone. We have signed or are in discussion with several companies regarding the sponsored development of CobOral drug delivery formulations of proprietary and non-proprietary actives.
- CobaCyte®-mediated cancer targeted delivery is a preclinical technology which makes use of the fact that cell surface receptors for vitamins such as B12 are often overexpressed by cancer cells. This technology uses nanopolymer constructs to deliver more anti-cancer drug to tumors while protecting normal tissues.

### **Products and Product Candidates**

We use our drug delivery technologies to develop the following products and product candidates:

## Access Drug Portfolio

<u>Compound</u>	<u>Originator</u>	<u>Technology</u>	<u>Indication</u>	<u>Clinical Stage (1)</u>
MuGard™	Access	Mucoadhesive liquid	Mucositis	Launched U.S. and EU
ProLindac™ (Polymer Platinate, AP5346) (2)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Thiarabine (4-thio Ara-C) (3)	Southern Research Institute	Small molecule	Cancer	Phase 1/2
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.

(3) Licensed from Southern Research Institute of Birmingham, Alabama.

## 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 \$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 Holding, B.V. under which SpePharm is to market MuGard in Europe. MuGard sales started in Europe in the second quarter of 2009. In January 2008, we signed a definitive licensing agreement with RHEI Pharmaceuticals, Inc., which was later sub-licensed to Jian An Pharmaceuticals, under which and Jian An will market 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 is ongoing. Also, in 2011, Mr. Anthony Mattola joined Access, as Vice President, Managed Care and Market Access, to assist with managed care, 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 has been launched in Germany, Italy, UK, Greece and the Nordic countries by our European commercial partner, SpePharm. We are working with our partners in Korea and China for registration and marketing.

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

##### Overview of ProLindac

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 sales in excess of \$2.7 billion in 2006. As is the case with all chemotherapeutic drugs, the use of such compounds is associated with serious systemic side effects. The drug development goal therefore is to enhance delivery of the active drug to the tumor and minimize the amount of active drug affecting normal organs in the body.

Utilizing a biocompatible water-soluble polymer (HPMA) as a drug carrier, 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.

In 2005, we completed a Phase 1 multi-center clinical study conducted in Europe, which enrolled 26 patients. The study was reported in a journal publication, *Cancer Chemotherapy and Pharmacology*, 60(4): 523-533 in 2007. The European trial was designed to identify the maximum tolerated dose, dose limiting toxicities, the pharmacokinetics of the platinum in plasma and the possible anti-tumor activity of ProLindac. The open-label, non-randomized, dose-escalation Phase 1 study was performed at two European centers.

Of the 26 patients, 10 were not evaluable for tumor response, principally due to withdrawal from the study prior to completing the required number of cycles. Of the 16 evaluable patients, 2 demonstrated a partial response, 1 experienced a partial response based on a biomarker and 4 experienced stable disease. One of the patients who attained a partial response had a melanoma with lung metastasis; a CT scan revealed a tumor decrease of greater than 50%. The other patient who responded had ovarian cancer; she had a reduction in lymph node metastasis and remission of a liver metastasis. The patient who experienced a partial response based on a biomarker was an ovarian cancer patient for whom Ca125 levels returned to normal. Also of note, a patient with cisplatin resistant cervical cancer showed a short lasting significant reduction in lung metastasis after 3 doses. However, due to toxicity, the patient could not be retreated to determine whether the partial response could be maintained.

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

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

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

ProLindac was well tolerated in an absolute sense and relative to commercially-available platinum therapies. We saw significant DACH platinum activity and efficacy in patients at the highest dose levels which we believe is very encouraging given that this study involved monotherapy in a heavily pretreated patient population that typically only respond to aggressive drug combinations. The DACH platinum activity level seen benchmarked favorably with published studies of monotherapy oxaliplatin in similar but less heavily pre-treated patient populations.

On August 3, 2009, we announced that we commenced a new clinical study of ProLindac in France. The study examined dose levels and regimens of ProLindac monotherapy in cancer patients, provided additional data to support design of combinations studies, and extended the safety database. Eight ovarian cancer patients were enrolled in the study at the end of 2009 and none experienced any acute adverse events.

#### Current Status of ProLindac

On January 7, 2010, based on the results of the monotherapy trials we announced the initiation of a study of ProLindac combined with Paclitaxel in second line treatment of platinum pretreated advanced ovarian cancer patients. This study is the first to look at the safety and efficacy of ProLindac in combination with other oncology agents. As seen with oxaliplatin, the efficacy of Diamino Cyclohexane (DACH) Platinum, the active principle in ProLindac, is evidenced mainly through their synergic association with multiple anticancer agents. The choice of Paclitaxel and ovarian cancer as the potential first NDA strategic choice to be explored is based on the results of the Paclitaxel/Oxaliplatin combination in the same clinical setting. This multi-center study of up to 25 evaluable patients is being conducted in Europe. The efficacy endpoint goal is to achieve a minimum of 63% response rate in the total of 25 evaluable patients the study is planning to accrue on a two-step design. We initiated this study of ProLindac combined with Paclitaxel in second line treatment of platinum pretreated advanced ovarian cancer patients in the fourth quarter of 2010.

We previously submitted an IND application to the FDA, and received clearance from the agency to proceed with a Phase 1 clinical study of ProLindac in combination with fluorouracil and leucovorin. The study is designed to evaluate the safety of ProLindac in combination with two standard drugs used to treat colorectal cancer and to establish a safe dose for Phase 2 clinical studies of this combination in colorectal cancer. We are currently evaluating various options for combination trials to be conducted, in the US or other countries.

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

##### Overview of Thiarabine

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

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



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

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

In the first phase 1 study, 26 patients with incurable advanced and/or metastatic solid tumors were enrolled. Out of 21 evaluable patients, 9 experienced stable disease (median duration 4.3 months, range 1.8-6.4 months).

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

A second solid tumor phase 1 trial was carried out to explore other schedules. Of the 27 evaluable patients, 7 patients (including bladder cancer and mesothelioma) achieved disease stabilization (median 3.7 months, range 1.9-5.4). The main toxicity was fatigue, which appeared to be schedule independent.

#### Current Status of Thiarabine

We believe the results seen for Thiarabine in leukemia and lymphoma preclinical models and the lymphopenia observed in clinical studies provides a strong rationale for further investigation of Thiarabine in leukemia and lymphoma patients. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and have initiated an additional Phase 2 clinical trial in adult AML, ALL and other indications. We also plan further Thiarabine clinical studies subject to funding or partnering.

#### **Drug Development Strategy**

We have a rich 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, Thiarabine 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 and Thiarabine. 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, certain preclinical testing and product production to research organizations, contract manufacturers and strategic partners as appropriate to achieve cost savings and accelerate our development programs. We 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.

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. We are also conducting an additional Phase 2 clinical study in France. Our licensees for MuGard are planning additional clinical studies to strengthen marketing claims.

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

We expended approximately \$3,349,000 and \$2,657,000 on research and development during the years 2010 and 2009, 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 hydroxypropylmethacrylamide (HPMA) 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 is also attached the drug to be delivered, or attached to a nanoparticle in which the drug is incorporated. Since many molecules of the drug are attached to a single polymer strand, or are incorporated in a single nanoparticle, 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.

## **Recent Developments**

On November 30, 2011, we closed the sale of approximately 575,000 shares of our common stock and warrants to purchase 575,000 shares of our common stock for gross proceeds of approximately \$834,000. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$2.00 per whole share exercisable for five years).

On November 17, 2011, we paid \$2.75 million of a secured promissory note. The remaining \$2.75 million of the secured promissory note is due September 13, 2012.

On November 10, 2011, we closed the sale of approximately 3.71 million shares of our common stock and warrants to purchase 3.71 million shares of our common stock for gross proceeds of approximately \$5.39 million. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at an exercise price of \$2.00 per whole share exercisable for five years).

On November 9, 2011, we announced we entered into an agreement with a pharmaceutical company in the RNAi industry to exploit our CobaCyte and CobOral technology for the delivery of RNAi therapeutics. We will provide the pharmaceutical company with CobOral and CobaCyte siRNA formulation for evaluation of gene knockdown following oral and intravenous administration. Any successful formulation developed will be jointly owned by the Parties and subject to a subsequent full licensing agreement.

### **Other Key Developments**

In various news releases over the past quarter we announced that MuGard has received reimbursement from many networks of leading insurance and pharmacy benefit managers throughout the U.S., including Aetna, Amerigroup, several state Anthem plans, Assurant Health, several Blue Cross Blue Shield state plans, Cigna, Express-Scripts, Harvard Pilgrim, Humana, Keystone, Tricare, United Healthcare, Wellspan Plus. Reimbursement coverage for MuGard is now available with standard pharmacy benefit copayment. Placement in pharmacy benefit plans will assist in driving increased reimbursement coverage in MuGard.

On September 7, 2011, we announced that we contracted with CuraScript, a healthcare subsidiary of Express Scripts, to expand our specialty pharmacy and third party logistics networks for MuGard. We also contracted with CuraScript Specialty Distribution to warehouse and serve as our specialty distributor and wholesaler for specialty pharmacy providers.

On August 5, 2011, we announced that we hired Edelman, the leading full service global public relations firm, to support our media outreach initiatives. Edelman will assist us in implementing a media communications outreach program primarily aimed at introducing MuGard and building awareness of its ability to treat oral mucositis

On July 28, 2011, we announced that we launched our patient reimbursement and support center for our lead product for oral mucositis, MuGard. Referred to as a HUB, the MuGard Patient Reimbursement and Support Center (MuGard PRSC) operated by eMax Health provides a centralized patient referral center that improves patient access to MuGard by enhancing product distribution and facilitating payment for MuGard by insurance carriers.

On July 12, 2011, we announced that we signed an agreement to restructure the outstanding \$5.5 million senior convertible promissory note scheduled to mature this year, that agreement was amended on August 15, 2011. The agreements provide for an extension of 50% of the note (\$2.75 million) until September 13, 2012, and require the payment of \$2.75 million to be paid promptly on the earlier of December 1, 2011 or upon the closing of an equity financing by the Company. If the initial \$2.75 million is not paid prior to December 1, 2011, then the full \$5.5 million plus accrued interest will become due and payable on December 13, 2011. The amendments provided the note holder with a security interest in certain of our assets and required an interest payment on August 15, 2011.

The amended agreement provides for the extension of 50% of the principal amount of the note (\$2.75 million) until September 13, 2012. The restructured agreement provides for the acceleration of payments to the note holder in the event of a corporate licensing or partnering transaction and also provides the note holder with a security interest in certain of our assets.

On June 27, 2011, we announced that RHEI Pharmaceuticals, our MuGard partner in China, has received the acceptance letter from the State Food and Drug Administration (SFDA) of China acknowledging all necessary documentation for MuGard has been submitted and accepted. Together with its marketing partner Jian An, RHEI Pharmaceuticals completed the required process required to satisfy all requirements to receive marketing approval in China and its other South East Asian territories. RHEI has advised Access of the next steps the SFDA will take to grant approval in its territories and anticipates receiving marketing approval in the second half of this year.

On May 24, 2011, we announced that we signed an agreement with eMAX Health Systems to expand the distribution network and to further support ongoing third party payer outreach programs for MuGard and advocate for reimbursement among commercial insurance carriers in the United States.

On May 10, 2011, we announced that we have made significant progress with our CobaCyte tumor-targeting technology. Using a new proprietary CobaCyte paclitaxel nanoparticle formulation, named Cobraxane™, our scientists have observed significant tumor growth inhibition in preclinical tumor models.

On December 10, 2010, we announced that we entered into definitive agreements for the sale of our common stock at a price of \$2.55 per share. We completed the sale of 3,102,000 shares of our common stock at \$2.55 per share and warrants to purchase 931,000 shares of our common stock at an exercise price of \$3.06 per share for an aggregate purchase price of \$7.9 million. Proceeds, net of cash issuance costs from the sale, were \$7.3 million.

On December 8, 2010, we announced that we entered into an agreement with a major global pharmaceutical company to test our oral insulin formulation based on our proprietary vitamin B-12-based CobOral Drug Delivery Technology. We will provide CobOral insulin to the pharmaceutical company.

On November 3, 2010, we announced that we have commenced a Phase 2 combination trial for our second generation DACH-platinum cancer drug, ProLindac, in platinum-sensitive ovarian-cancer patients. This trial is an open-label, Phase 2 study of ProLindac given intravenously with paclitaxel. The combination trial will be conducted in up to eight European participating centers.

On November 1, 2010, we announced that we have been awarded \$1.5 million in government grants. Under the recently enacted Patient Protection and Affordable Care Act, cash grants were awarded to Qualifying Therapeutic Discovery Projects that showed significant potential in producing new and cost-saving therapies, support job growth and increase U.S. competitiveness. Grants were awarded through a competitive application process, and seven out of eight of our applications were awarded.

On October 27, 2010, we announced that we have entered into a pre-licensing feasibility agreement with a biopharmaceutical company to develop an oral formulation of an undisclosed prostate cancer compound utilizing its proprietary vitamin B-12-based CobOral Drug Delivery Technology. We will develop CobOral formulations for testing by the biopharma company. Though the terms of the agreement have not been disclosed, we have indicated that any successful formulation developed will be jointly owned by the parties and subject to a subsequent full licensing agreement.

On October 20, 2010, we announced that we have submitted additional patent applications, covering our Cobalamin-mediated oral drug delivery technology formulations of many global top-100 injectable drugs, as a result of the growing interest surrounding our proprietary oral delivery technology. The patents cover oral formulations of leading injectables, like bevacizumab (Avastin®), trastuzumab (Herceptin®), adalimumab (Humira®), etanercept (Enbrel®), insulin glargine (Lantus®), and many others. In addition, we rebranded our Cobalamin-mediated oral drug delivery technology as CobOral® delivery technology.

On September 29, 2010, we announced that we have made significant progress with our proprietary Cobalamin-targeted drug-delivery program for siRNA therapies. As a result of the continued advancements made with our Cobalamin program, we rebranded the targeted-drug delivery technology as CobaCyte; and submitted additional patent applications for its improved CobaCyte formulations, including siRNA compositions.

On September 21, 2010, we announced we signed a supply agreement for MuGard with RHEI Pharmaceuticals, Inc. (“RHEI”), a specialty pharmaceutical company focused on bringing proprietary medicines to the China market. Under the agreement we are required to ensure manufacturing capacity of up to a minimum of \$30 million of product in the licensed territories. Coinciding with the signing of the above agreement, we also approved a sub-license agreement between RHEI Pharmaceuticals and Jian An Pharmaceuticals (“Jian An”) Limited in Shenzhen, China in an effort to leverage Jian An’s extensive sales, marketing and regulatory infrastructure for the launch of MuGard in China and Taiwan.



On August 2, 2010, we announced we initiated a Phase 1/2 dose-escalating study of our proprietary, anti-cancer drug, Thiarabine, a nucleoside analogue for patients with hematologic malignancies (cancers of the blood). The primary objective of the study is to determine the maximum tolerated dose (MTD) in two different dosing schedules with various leukemias and lymphomas and recommended Phase II dose. The program is being led by Hagop Kantarjian, M.D., Chair of the Department of Leukemia at The University of Texas MD Anderson Cancer Center in Houston, Texas.

On July 20, 2010, we announced we had signed an exclusive specialty distribution agreement with BioScrip, Inc. for MuGard. The agreement aligns us with comprehensive access to BioScrip's nationwide distribution platform and the ability to leverage their extensive physician relationships, 110 BioScrip specialty pharmacies, mail distribution capability and diversified payor network.

On July 15, 2010, we announced that we had entered into a pre-licensing feasibility agreement with a leading biotechnology company to develop an oral formulation of its currently-marketed, proprietary injectable drugs. We will utilize our proprietary CobOral Drug Delivery Technology to develop oral formulation of the drug for pre-clinical testing.

On April 13, 2010, we announced that we had completed our first commercial scale production run of MuGard in North America at Accupac, Inc. manufacturing facilities.

On March 30, 2010, we announced that we signed a collaborative development agreement with bioRASI, LLC to facilitate clinical development for our CobOral based oral insulin and CobaCyte based products.

On March 11, 2010, we announced that we had received reports of significant bioavailability of orally delivered insulin in two independently-conducted animal studies with our CobOral Drug Delivery Technology.

On January 22, 2010, we announced the sale of approximately 2.10 million shares of our common stock and warrants to purchase approximately 1.04 million shares of our common stock for gross proceeds of approximately \$6.3 million. We sold these shares and warrants as a combined unit for \$3.00 per unit (each unit consisting of one share and a warrant to purchase 0.5 shares of common stock). The exercise price of the warrants is \$3.00 per share. Proceeds, net of cash issuance costs from the sale, were \$5.8 million.

On January 7, 2010, we announced that we completed enrollment and evaluation of the last additional cohort of patients in the ongoing clinical study of ProLindac as a monotherapy in ovarian cancer patients who received at least two prior platinum based treatment regimens. The additional cohort of 8 patients received the ProLindac batch made by an improved scalable process, which will be used on a larger scale for future clinical and commercial supplies. None of the 8 patients experienced any acute significant adverse events, while treatment had the same beneficial pharmacodynamic effect seen in the first 26 patients treated with the former ProLindac production batch; clinically relevant sustained biomarker decrease (responses by Rustin's criteria) and disease stabilization were seen in several patients. The overall results of our Phase 1/2 exploratory single agent ProLindac study have helped define multiple safe dosing regimens, while the level of patient cohort accrued in the study antitumor activity was as expected in this very heavily pretreated patient cohort.

## **Patents**

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

Two U.S. patents have issued and one European has been issued and one European patent application is under review for our mucoadhesive liquid technology. Our patent applications cover a range of products utilizing our mucoadhesive liquid technology for the management of the various phases of mucositis.

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

Thiarabine is subject to two process patents that expire in 2018, one use patent that expires in 2019, as well an additional patent which expires in 2027.

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

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

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:

- Mucoadhesive technology in 2030,
- ProLindac™ in 2021,
- Thiarabine in 2018, and
- CobaCyte/CobOral mediated technology between 2012 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 IND with the FDA, which must become effective pursuant to FDA regulations before human clinical trials may commence, numerous phases of clinical testing and the FDA approval of a New Drug Application (NDA) prior to commercial sale.

Preclinical tests are conducted in the laboratory, usually involving animals, to evaluate the safety and efficacy of the potential product. The results of preclinical tests are submitted as part of the IND application and are fully reviewed by the FDA prior to granting the sponsor permission to commence clinical trials in humans. All trials are conducted under International Conference on Harmonization (ICH), good clinical practice guidelines. All investigator sites and sponsor facilities are subject to FDA inspection to insure compliance. Clinical trials typically involve a three-phase process. Phase 1 the initial clinical evaluations, consists of administering the drug and testing for safety and tolerated dosages and in some indications such as cancer and HIV, as preliminary evidence of efficacy in humans. Phase 2 involves a study to evaluate the effectiveness of the drug for a particular indication and to determine optimal dosage and dose interval and to identify possible adverse side effects and risks in a larger patient group. When a product is found safe, an initial efficacy is established in Phase 2, it is then evaluated in Phase 3 clinical trials. Phase 3 trials consist of expanded multi-location testing for efficacy and safety to evaluate the overall benefit to risk index of the investigational drug in relationship to the disease treated. The results of preclinical and human clinical testing are submitted to the FDA in the form of an NDA for approval to commence commercial sales.

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

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

## **Competition**

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



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

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

ActoGeniX N.V., BioAlliance Pharma S.A., EUSA Pharma, NephRx, PolyMEDix, Inc., SciClone Pharmaceuticals, 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 platinum:

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

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

- 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.

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

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 January 18, 2012, we had thirteen full-time employees, four of whom have advanced scientific degrees. We have never experienced employment-related work stoppages and consider that we maintain good relations with our personnel. In addition, to complement our internal expertise, we have contracts with scientific consultants, contract research organizations and university research laboratories that specialize in various aspects of drug development including clinical development, regulatory affairs, toxicology, process scale-up and preclinical testing.

### **Web Availability**

We make available free of charge through our website, [www.accesspharma.com](http://www.accesspharma.com), our annual reports on Form 10-K and other reports that we file with the Securities and Exchange Commission as well as certain of our corporate governance policies, including the charters for the Board of Directors' audit, compensation and nominating and corporate governance committees and 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.

## **DESCRIPTION OF PROPERTY**

We maintain one facility of approximately 9,000 square feet for administrative offices and laboratories in Dallas, Texas. We have a lease agreement for the facility, which terminates in December 2012. Adjacent space may be available for expansion which we believe would accommodate growth for the foreseeable future.

We also maintain approximately 2,000 square feet of a business office suites for administrative offices in New York, New York. We have a lease agreement for the facility, which terminates in August 2012.

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

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

None.

## DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

The following table sets forth the Directors, Executive Officers, and Key Employees of Access along with their respective ages and positions and is as follows:

<u>Name</u>	<u>Age</u>	<u>Title</u>
Steven H. Rouhandeh	54	Chairman of the Board*
Jeffrey B. Davis	48	Chief Executive Officer, Director*
Esteban Cvitkovic, M.D.	62	Vice Chairman – Europe
Mark J. Ahn, Ph.D.	49	Director
Mark J. Alvino	44	Director
Stephen B. Howell, M.D.	67	Director
David P. Nowotnik, Ph.D.	62	Senior Vice President Research & Development
Frank A. Jacobucci	50	Vice President, Sales and Marketing
Phillip S. Wise	53	Vice President, Business Development & Strategy
Stephen B. Thompson	58	Vice President, Chief Financial Officer, Treasurer, Secretary

\* Appointed to the board of directors by SCO Capital Partners LLC (“SCO”) pursuant to a Director Designation Agreement between SCO and Access.

None of our directors, officers, affiliates or promoters has, within the past five years, filed any bankruptcy petition, been convicted in or been the subject of any pending criminal proceedings, or is any such person the subject of any order, judgment or decree involving the violation of any state or federal securities laws.

The following is a brief account of the business experience during the past five years of each of our directors and executive officers, including principal occupations and employment during that period and the name and principal business of any corporation or other organization in which such occupation and employment were carried on.

*Mr. Steven H. Rouhandeh* became a director and Chairman of the Board on March 4, 2008. He is a Chief Investment Officer of SCO Capital Partners, a group of New York based life sciences funds. He possesses a diverse background in financial services that includes experience in asset management, corporate finance, investment banking and law. He has been active throughout recent years as an executive in venture capital and as a founder of several companies in the biotech field. His experience also includes positions as Managing Director of a private equity group at Metzler Bank, a private European investment firm and Vice President, Investment Banking at Deutsche Morgan Grenfell. Mr. Rouhandeh was also a corporate attorney at New York City-based Cravath, Swaine & Moore. Mr. Rouhandeh holds a J.D., from Harvard Law School, Harvard University and B.A. Government, Economics, from Southern Illinois University. Mr. Rouhandeh’s qualifications to serve our Board include his institutional knowledge of our Company and his extensive domestic and international financial experience in the healthcare industry. In addition, his expertise as founder and Chief Investment Officer of SCO Capital Partners, L.P. is important to the Company in all areas of operation and development including corporate finance, investment banking and business strategy.

*Mr. Jeffrey B. Davis* became a director in March 2006. Mr. Davis became our Chief Executive Officer on December 26, 2007. Previously, Mr. Davis was Chairman of the Board and Chairman of the Compensation Committee of the Board. Mr. Davis currently serves as President of SCO Financial Group LLC and has been employed by SCO since 1997. Previously, Mr. Davis served in senior management at a publicly traded healthcare technology company. Prior to that, Mr. Davis was an investment banker with various Deutsche Bank banking organizations, both in the U.S. and Europe. Mr. Davis also served in senior marketing and product management positions at AT&T Bell Laboratories, where he was also a member of the technical staff, and at Philips Medical Systems North America. Mr. Davis is currently on the board of Uluru, Inc., a public biotechnology company. Mr. Davis holds a B.S. in biomedical engineering from Boston University and an M.B.A. degree from the Wharton School, University of Pennsylvania. Mr. Davis’ qualifications to serve our Board include his current experience as our CEO leading the day to day operations of our Company. In addition, Mr. Davis’ qualifications include his prior experience serving our Board since 2006, as well as his extensive domestic and international financial experience in the healthcare industry.





*Dr. Esteban Cvitkovic* became our director in February 2007 as Vice Chairman (Europe) and is also a consultant to us as Senior Director, Oncology Clinical Research & Development. Recently, Dr. Cvitkovic co-founded the new contract research organization (CRO), Oncology Therapeutic Development. The oncology-focused CRO, Cvitkovic & Associés Consultants (CAC), founded by Dr. Cvitkovic 11 years ago and which he developed from a small oncology consultancy to a full-service CRO, was sold to AAIPharma to become AAIOncology in 2007. In addition, he maintains a part-time academic practice including teaching at the hospitals Beaujon and St. Louis in Paris. Dr. Cvitkovic is Scientific President of the FNAB, a foundation devoted to the furthering of personalized cancer treatments. Together with a small number of collaborators, he has recently co-founded Oncoethix, a biotech company focused on licensing and co-development of anti-cancer molecules. Dr. Cvitkovic has authored more than 200 peer-reviewed articles and 600 abstracts focused on therapeutic oncology development. His international career includes staff and academic appointments at Memorial Sloan Kettering Cancer Center (New York), Columbia Presbyterian (New York), Instituto Mario Negri (Milan), Institut Gustave Roussy (Villejuif), Hôpital Paul Brousse (Villejuif) and Hôpital St. Louis (Paris). Dr. Cvitkovic's qualifications to serve our Board include his technical expertise and strong commitment to promoting and advancing innovation in the healthcare industry. In addition, Dr. Cvitkovic's qualifications include experience as a medical doctor in oncology and his executive skills as a founder of several contract research organizations.

*Mark J. Ahn, Ph.D.* became a director in September 2006 and is chairman of the Compensation Committee. Dr. Ahn is also a member of the Audit Committee and the Nominating & Corporate Governance Committee. Dr. Ahn is Principal at Pukana Partners, Ltd. since 2009 and is President and Chief Executive Officer and Director of RXi Pharmaceuticals Corporation since March 31, 2011. Dr. Ahn holds an academic position at the Atkinson Graduate School of Management, Willamette University. Dr. Ahn was Professor and Chair, Science & Technology Faculties of Commerce & Administration Science at Victoria University of Wellington, New Zealand from 2007 to 2009. Dr. Ahn was President and Chief Executive Officer and a member of the board of directors of Hana Biosciences, Inc. from 2003 to 2007. Prior to joining Hana, from 2001 to 2003, he served as Vice President, Hematology and corporate officer at Genentech, Inc. where he was responsible for commercial and clinical development of the Hematology franchise. From 1991 to 2001, Dr. Ahn was employed by Amgen and Bristol-Myers Squibb Company holding a series of positions of increasing responsibility in strategy, general management, sales & marketing, business development, and finance. He has also served as an officer in the U.S. Army. Dr. Ahn is a Henry Crown Fellow at the Aspen Institute, founder of the Center for Non-Profit Leadership, a director of TransMolecular, Inc., a privately held biotechnology company focused on neuroncology, and a member of the Board of Trustees for the MEDUNSA (Medical University of South Africa) Trust. Dr. Ahn received a B.A. in History and an M.B.A. in Finance from Chaminade University. He was a graduate fellow in Economics at Essex University, and has a Ph.D. in Business Administration from the University of South Australia. Dr. Ahn's qualifications to serve on our Board include his strong executive leadership, management, financial and operational skills in successfully leading Hana Biosciences and his strong commitment to promoting and advancing innovation in the science field.

*Mr. Mark J. Alvino* became a director in March 2006 initially as a designee of SCO Capital Partners LLC and is chairman of the Audit Committee. Mr. Alvino is also a member of the Nominating and Corporate Governance Committee. Mr. Alvino is currently Managing Director for Griffin Securities and has been in this position since 2007. Mr. Alvino was Managing Director for SCO Financial Group LLC from 2002 to 2007. Mr. Alvino was a member of the board of directors of MacroChem Corporation from 2007 until February 2009. He previously worked at Feinstein Kean Healthcare, an Ogilvy Public Relations Worldwide Company. There he was Senior Vice President, responsible for managing both investor and corporate communications programs for many private and public companies and acted as senior counsel throughout the agency's network of offices. Prior to working at FKH, Mr. Alvino served as Vice President of Investor Relations and managed the New York Office of Allen & Caron, Inc., an investor relations agency. His base of clients included medical devices, biotechnology, and e-healthcare companies. Mr. Alvino also spent several years working with Wall Street brokerages including Ladenburg, Thallman & Co. and Martin Simpson & Co. Mr. Alvino's qualifications to serve our Board include his leadership skills and his experience in the areas of financial management and business strategy in the biopharmaceutical field.

*Stephen B. Howell, M.D.* has served as our director since 1996. Dr. Howell is a member of the Compensation Committee of the Board. Dr. Howell is a Professor of Medicine at the University of California, San Diego, and director of the Cancer Pharmacology Program of the UCSD Cancer Center. Dr. Howell is a recipient of the Milken Foundation prize for his contributions to the field of cancer chemotherapy. He has served on the National Research Council of the American Cancer Society and is on the editorial boards of multiple medical journals. Dr. Howell founded DepoTech, Inc. and served as a member of its board of directors from 1989 to 1999. Dr. Howell served on the board of directors of Matrix Pharmaceuticals from 2000 to 2002. Dr. Howell received his A.B. at the University of Chicago and his M.D. from Harvard Medical School. Dr. Howell's qualifications to serve our Board include his technical expertise and strong commitment to promoting and advancing innovation in the healthcare industry. In addition, Dr. Howell's qualifications include experience as a medical doctor in oncology, his experience as director of several biotech companies and his executive skills and experience as a founder of a biotech company.

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

*Mr. Frank A. Jacobucci* has been our Vice President Sales and Marketing since December 2009. Mr. Jacobucci was President and COO of Milestone Biosciences, LLC from 2007 to 2009. He was Vice President Sales/Marketing of Claims Resolution Center Oncology Services in 2007, Area Sales Manager-Eastern Seaboard of Precision Therapeutics, Inc. from 2006-2007 and Sales Trainer/Field Sales Advisor/Senior Sales Executive of MGI Pharma from 2003 to 2006. Mr. Jacobucci has had manager positions with increasing responsibilities from 1990 to 2003 with various other pharmaceutical and other companies. He holds a B.S. degree from University of Nevada, Las Vegas.

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

*Mr. Stephen B. Thompson* has been our 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.

### **Committees of the Board of Directors**

The Board established an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. Each of the committees of the Board acts pursuant to a separate written charter adopted by the Board.

The Audit Committee is currently comprised of Mr. Mark J. Alvino (chairman) and Mr. Mark J. Ahn. The Board has determined that Mr. Alvino, the chairman of the Audit Committee, is an "audit committee financial expert," under applicable SEC rules and regulations. The Audit Committee's responsibilities and duties are among other things to engage the independent auditors, review the audit fees, supervise matters relating to audit functions and review and set internal policies and procedure regarding audits, accounting and other financial controls. The Board has determined that Dr. Ahn and Mr. Alvino are independent under applicable NYSE Amex rules and regulations. The Audit Committee acts pursuant to a written charter which is available on our website at [www.accesspharma.com](http://www.accesspharma.com).

The Compensation Committee is currently comprised of Mr. Mark J. Ahn (chairman) and Dr. Stephen B. Howell. Mr. Ahn and Dr. Howell are non-employee directors under applicable SEC rules, and are “outside” directors under Internal Revenue Code Section 162(m). Mr. Ahn and Dr. Howell are independent under applicable NYSE Amex rules and regulations. The Compensation Committee acts pursuant to a written charter which is available on our website at [www.accesspharma.com](http://www.accesspharma.com).

The Nominating and Corporate Governance Committee is currently comprised of Mark Ahn, PhD and Mark J. Alvino. All committee members are independent under applicable NYSE Amex rules and regulations. The Nominating and Corporate Governance Committee is responsible for, among other things, considering potential Board members, making recommendations to the full Board as to nominees for election to the Board, assessing the effectiveness of the Board and implementing our corporate governance guidelines. The Nominating and Corporate Governance Committee acts pursuant to a written charter which is available on our website at [www.accesspharma.com](http://www.accesspharma.com).

### **Director Independence**

The Board has determined that each of Dr. Ahn, Mr. Alvino and Dr. Howell are independent under applicable NYSE Amex rules. Based on the fully-diluted common stock ownership of SCO Capital Partners LLC and its affiliates, the Board has determined we are a “Controlled Company” under applicable NYSE Amex rules and regulations and therefore under applicable NYSE Amex rules and regulations, we are not required to comply with certain director independence requirements. Although we are not currently listed on NYSE Alternext US, and are instead listed on the OTCBB, we have chosen to follow the NYSE Amex rules and regulations governing director independence.

### **Board Leadership Structure**

The Board has no set policy with respect to the separation of the officers of Chairman and the Chief Executive Officer. Currently, Steven H. Rouhandeh serves as our Chairman and Jeffrey B. Davis serves as our Chief Executive Officer. There are currently no lead independent directors serving on the Board.

Our Board leadership structure is commonly utilized by other public companies in the United States, and we believe that it is effective for us. This leadership structure is appropriate for us given the size and scope of our business, the experience and active involvement of our independent directors, and our corporate governance practices, which include regular communication with and interaction between and among the Chief Executive Officer and the Chief Financial Officer and the independent directors. Of the six members of our Board, three are independent from management. At this time, we believe that having a separate Chairman and Chief Executive Officer and independent chairs for each of our Board committees provides the best form of leadership for us.

### **Board of Director’s Role in Risk Oversight**

The Board is responsible for overseeing our management and operations, including overseeing our risk assessment and risk management functions. We believe that our directors provide effective oversight of risk management functions. On a regular basis we perform a risk review wherein the management team evaluates the risks we expect to face in the upcoming year and over a longer term horizon. From this risk assessment plans are developed to deal with the risks identified. The results of this risk assessment are provided to the Board for their consideration and review. In addition members of our management periodically present to the Board the strategies, issues and plans for the areas of our business for which they are responsible. While the Board oversees risk management, our management is responsible for day-to-day risk management processes. Additionally, the Board requires that management raise exceptional issues to the Board. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that the Board leadership structure supports this approach.

## Code of Business Conduct and Ethics

We have adopted a written Code of Business Conduct and Ethics that applies to all of our directors, officers and employees. A copy of our Code of Business Conduct and Ethics is available on our website at [www.accesspharma.com](http://www.accesspharma.com) and print copies are available to any shareholder that requests a copy. Any amendment to the Code of Business Conduct and Ethics or any waiver of the Code of Business Conduct and Ethics will be disclosed on our website at [www.accesspharma.com](http://www.accesspharma.com) promptly following the date of such amendment or waiver.

## EXECUTIVE COMPENSATION

The following table sets forth the aggregate compensation paid to our CEO and our next two most highly paid executive officers whose aggregate salary and bonus exceeded \$100,000 for services rendered in all capacities for the fiscal years ended December 31, 2011 and 2010.

### Summary Compensation Table

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Stock</u>	<u>Option</u>	<u>All Other</u>	<u>Total (\$)</u>
		<u>(1)</u>	<u>Awards (\$)</u>	<u>Awards (\$)</u>	<u>Compensation</u>	
		<u>(1)</u>	<u>(2)</u>	<u>(3)</u>	<u>(4)</u>	
Jeffrey B. Davis	2011	\$ 290,000	\$ -	\$ -	\$ -	\$ 290,000
Chief Executive Officer	2010	240,000	-	-	-	240,000
David P. Nowotnik, Ph.D.						
Senior Vice President Research	2011	\$ 309,000	\$ -	\$ 205,000	\$ 13,000	\$ 527,000
and Development	2010	287,000	-	178,000	2,000	467,000
Frank S. Jacobucci						
Vice President, Sales and	2011	\$ 265,000	\$ 52,000	\$ 74,000	\$ -	\$ 391,000
Marketing	2010	240,000	62,000	60,000	-	362,000

(1) Includes amounts deferred under our 401(k) Plan.

(2) Represents expense recognized in 2011 and 2010 for the fair value of common stock vested. The fair value used is the stock price on the date the common stock is vested.

(3) The value listed in the above table represents the fair value of the options granted in prior years that was recognized in 2011 and 2010 under ASC 718. Fair value is calculated as of the grant date using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards made on the date of grant is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. Our assumptions in determining fair value are described in note 11 to our audited financial statements for the year ended December 31, 2010, included in our annual report on Form 10-K.

(4) Amounts reported for fiscal years 2011 and 2010 consist of: (i) amounts we contributed to our 401(k) Plan with respect to each named individual, and (ii) amounts we paid for group term life insurance for each named individual.

### Outstanding Equity Awards at Fiscal Year-End

The following table summarizes the aggregate number of option awards held by our named executive officers at December 31, 2011. There were no outstanding stock awards held by any such officers at December 31, 2011:

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price \$(1)	Option Expiration Date
Jeffrey B. Davis <sup>(2)</sup>	25,000	-	-	0.63	08/17/16
David P. Nowotnik, Ph.D. <sup>(3)</sup>	-	50,000	-	2.27	05/26/21
	133,334	66,666		2.79	02/01/20
	75,000	-		1.38	05/27/19
	45,836	4,164		3.00	05/21/18
	100,000	-		0.63	08/17/16
	8,000	-		11.60	05/23/15
	5,000	-		29.25	01/23/14
	7,000	-		10.10	01/30/13
	10,000	-		18.65	03/22/12
Frank S. Jacobucci <sup>(4)</sup>	-	50,000	-	2.27	05/26/21
	69,375	20,625		3.02	12/01/19

(1) On December 31, 2011, the closing price of our common stock as quoted on the OTC Bulletin Board was \$1.44.

(2) Jeffrey B. Davis' employment agreement started January 4, 2008. The options included in this table were granted to him as a director before he became CEO. Mr. Davis does not have any stock options granted to him as CEO.

(3) Dr. Nowotnik's options to purchase 50,000 shares of common stock will be fully vested in May 2015; 200,000 shares of common stock will be fully vested in February 2013 and 50,000 shares of common stock will be fully vested in April 2012.

(4) Mr. Jacobucci's options to purchase 50,000 shares of common stock will be fully vested in May 2015 and 90,000 shares of common stock will be fully vested in November 2012.

## Compensation Pursuant to Agreements and Plans

### *Employment Agreements*

#### President and Chief Executive Officer

We are a party to an employment agreement, with Jeffrey B. Davis, who was named by the Board as our Chief Executive Officer, effective as of December 26, 2007. Mr. Davis' employment agreement, dated January 4, 2008, was amended April 9, 2008. Pursuant to the terms of his employment agreement, Mr. Davis was paid an annual salary of \$290,000 in 2011 and \$240,000 in 2010. Under this agreement, Mr. Davis is currently entitled to receive an annual base of \$325,000. Mr. Davis does not currently have any stock options resulting from his employment with us. Mr. Davis was previously awarded stock options to purchase 25,000 shares of our common stock prior to becoming CEO. Mr. Davis is entitled to similar employee benefits as Access' other executive officers.

#### Senior Vice President

We entered into to an employment agreement with David P. Nowotnik, Ph.D., our Senior Vice President Research and Development, on February 1, 2010. Under this agreement, Dr. Nowotnik is entitled to receive an annual base salary of \$319,000, subject to adjustment by the Board. Dr. Nowotnik is also entitled to receive:

- a bonus payable in cash related to the attainment of reasonable performance goals specified by the Board;

- options to purchase 200,000 shares of our common stock at an exercise price of \$2.79 per share, with one third options vesting on February 1, 2011 and the remaining two thirds options vesting ratably on February 1, 2012 and February 1, 2013;

- stock options issued from time to time at the discretion of the Board;
- disability benefits up to six months; and
- medical insurance, term life insurance of \$319,000 and long-term disability insurance.

On May 31, 2009 and until February 1, 2010, Dr. Nowotnik was a party in a Transition Service Agreement with us pursuant to which his current salary was \$10,000 per month. He was also granted options to purchase 75,000 shares of common stock at \$1.38, of which all options are now vested. The transition services agreement continued a provision for Dr. Nowotnik's healthcare coverage.

#### Vice President Marketing and Sales

We entered into to an employment agreement with Frank S. Jacobucci, our Vice President Marketing and Sales, on December 1, 2009. Under this agreement, Mr. Jacobucci is entitled to receive an annual base salary of \$275,000, subject to adjustment by the Board. Mr. Jacobucci is also entitled to receive:

- a bonus payable in cash related to the attainment of reasonable performance goals specified by the Board;
- grant of 100,000 restricted shares of our common stock, with one quarter of the Common stock vested on the grant date and the remaining common stock vesting pro rata monthly on the first of the month each month for the next 36 months. All of the common stock will be vested November 1, 2012.
- options to purchase 90,000 shares of our common stock at an exercise price of \$3.02 per share, with one quarter options vested on the grant date and the remaining options vesting pro rata monthly on the first of each month for the next 36 months. All of the options will be vested November 1, 2012.
- stock options issued from time to time at the discretion of the Board;
- disability benefits up to six months; and
- medical insurance, term life insurance of \$275,000 and long-term disability insurance.

#### ***Compensation of Directors***

##### *Director Compensation Table - 2011*

The table below represents the compensation paid to our outside directors during the year ended December 31, 2011:

Name	Fees earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$)(1)	All Other Compensation (\$)	Total (\$)
Mark J. Ahn, PhD (2)	-	-	67,000	-	67,000
Mark J. Alvino (3)	-	-	67,000	-	67,000
Esteban Cvitkovic, MD (4)	-	71,000	48,000	145,000	264,000
Jeffrey B. Davis (5)	-	-	-	-	-
Stephen B. Howell, MD (6)	-	-	67,000	-	67,000
Steven H. Rouhandeh (7)	-	-	-	-	-

- (1) The value listed represents the fair value of the options recognized as expense under ASC 718 during 2011. Fair value is calculated as of the grant date using a Black-Scholes (“Black-Scholes”) option-pricing model. The determination of the fair value of share-based payment awards made on the date of grant is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. Our assumptions in determining fair value are described in note 11 to our audited financial statements for the year ended December 31, 2010, included in our Annual Report on Form 10-K.
- (2) Represents expense recognized in 2011 in respect of options to purchase 35,000 shares of our common stock based on a grant date fair value of \$67,000. Dr. Ahn had options to purchase 131,000 shares of our common stock at December 31, 2011.
- (3) Represents expense recognized in 2011 in respect of options to purchase 35,000 shares of our common stock based on a grant date fair value of \$67,000. Mr. Alvino had options to purchase 71,000 shares of our common stock at December 31, 2011.
- (4) Represents expense recognized in 2011 in respect of options to purchase 25,000 shares of our common stock based on a grant date fair value of \$48,000. Includes \$71,000 Dr. Cvitkovic received for scientific consulting services in 2011 for 35,000 shares of our common stock and \$145,000 Dr. Cvitkovic received for scientific consulting services in 2011. Dr. Cvitkovic had options to purchase 106,000 shares of our common stock at December 31, 2011.
- (5) Mr. Davis served as our CEO during 2011 and did not receive board fees or options. Mr. Davis’ salary and employment agreement are discussed in the Summary Compensation Table and Compensation Pursuant to Agreements and Plans – Employment Agreements – President and Chief Executive Officer. Mr. Davis had options to purchase 25,000 shares of our common stock at December 31, 2011.
- (6) Represents expense recognized in 2011 in respect of options to purchase 35,000 shares of our common stock based on a grant date fair value of \$67,000. Dr. Howell had options to purchase 141,700 shares of our common stock at December 31, 2011.
- (7) Mr. Rouhandeh does not have any options or warrants outstanding at December 31, 2011. See also the Security Ownership of Certain Beneficial Owners and Management.

### Compensation of Directors

Each director who is not also an Access employee receives a quarterly fee of \$3,000 and also receives \$1,000 per quarter in aggregate for all the committees of which he is a member. The Chairman of the Board is paid an additional \$1,000 per quarter and the Chairman of each of the Audit and Compensation Committee is paid an additional \$500 per quarter. Each director will have \$2,000 deducted from his fee if the director misses more than one Board meeting, and \$1,000 deducted per committee meeting not attended. In addition, we reimbursed each director, whether an employee or not, the expense of attending Board and committee meetings. Each non-employee director is also entitled to receive options to purchase 2,500 shares of common stock on the date of each annual meeting of stockholders and options to purchase 25,000 shares of common stock when he is first appointed as a director. The Board granted options to purchase 35,000 shares to each outside director for 2011 instead of the options to purchase 2,500 shares as has been granted historically.

During 2011, each of our directors elected to receive options to purchase 25,000 shares of common stock in lieu of their quarterly fees and annual stock grants. For each committee of which a director was a member, he received options to



purchase 10,000 shares of our common stock.

## LEGAL PROCEEDINGS

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

### SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

#### Security Ownership of Certain Beneficial Owners and Management

Based solely upon information made available to us, the following table sets forth certain information with respect to the beneficial ownership of our common stock and preferred stock as of January 18, 2012 by (i) each person who is known by us to beneficially own more than five percent of any class of our capital stock; (ii) each of our directors; (iii) each of our named executive officers; and (iv) all our executive officers and directors as a group. Beneficial ownership as reported in the following table has been determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended. The address of each holder listed below, except as otherwise indicated, is c/o Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, Texas 75207.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership of Common Stock <sup>(1)</sup>	Percent of Class	Amount and Nature of Beneficial Ownership Preferred Stock (on an as-if-converted basis)	Percent of Class	Amount and Nature of Beneficial Ownership of All Classes of Stock	Percent of Class
Steven H. Rouhandeh <sup>(2)</sup>	-	*	-	*	-	*
Jeffrey B. Davis <sup>(3)</sup>	36,000	*	-	*	36,000	*
Mark J. Ahn, Ph. D. <sup>(4)</sup>	141,000	*	-	*	141,000	*
Mark J. Alvino <sup>(5)</sup>	71,000	*	-	*	71,000	*
Esteban Cvitkovic, M.D. <sup>(6)</sup>	306,000	1.3%	-	*	306,000	*
Stephen B. Howell, M.D. <sup>(7)</sup>	151,422	*	-	*	151,422	*
David P. Nowotnik, Ph.D. <sup>(8)</sup>	389,286	1.6%	-	*	389,286	*
Frank S. Jacobucci <sup>(9)</sup>	146,450	*	-	*	146,450	*
SCO Capital Partners LLC, SCO Capital Partners LP, and Beach Capital LLC <sup>(10)</sup>	9,535,092	31.8%	14,642,278	72.3%	24,177,370	48.2%
Ayer Capital Partners Master Fund, LP <sup>(11)</sup>	5,056,880	9.6%	-	-	5,056,880	5.4%
Larry N. Feinberg <sup>(12)</sup>	1,222,443	5.0%	3,015,931	14.9%	4,238,374	9.4%
Lake End Capital LLC <sup>(13)</sup>	1,059,601	4.3%	1,640,829	8.1%	2,700,430	6.0%
All Directors and Executive Officers as a group (consisting of 8 persons) <sup>(14)</sup>	1,241,158	5.0%	-	*	1,241,158	2.7%

\* - Less than 1%

(1) Includes our outstanding shares of common stock held plus all shares of common stock issuable upon exercise of options, warrants and other rights exercisable within 60 days of January 18, 2012.

(2) Steven H. Rouhandeh, our Chairman, is also Chairman of SCO Financial Group LLC. His address is c/o SCO Capital Partners LLC, 1325 Avenue of the Americas, 27th Floor, New York, NY 10019. SCO Financial Group LLC and affiliates (SCO Capital Partners LP and Beach Capital LLC) are known to beneficially own an aggregate of 3,481,805 shares of our common stock, warrants to purchase an aggregate of 6,053,287 shares of our common stock and 14,642,278 shares of common stock issuable upon conversion of Series A Cumulative Convertible Preferred Stock. Mr. Rouhandeh disclaims beneficial ownership of all such shares except to the

extent of his pecuniary interest therein.

- (3) Mr. Davis, our Chief Executive Officer, is known to beneficially own an aggregate of 7,333 shares of our common stock, presently exercisable options for the purchase of 25,000 shares of our common stock pursuant to the 2005 Equity Incentive Plan and 3,667 shares of common stock underlying warrants held by Mr. Davis.
- (4) Dr. Ahn, our Director, is known to beneficially own an aggregate of 10,000 shares of our common stock, presently exercisable options for the purchase of 131,000 shares of our common stock pursuant to the 2005 Equity Incentive Plan.
- (5) Mr. Alvino, our Director, is known to beneficially own presently exercisable options for the purchase of 71,000 shares of our common stock pursuant to the 2005 Equity Incentive Plan.
- (6) Dr. Cvitkovic, our Director, is known to beneficially own presently exercisable options for the purchase of 106,000 shares of our common stock pursuant to the 2005 Equity Incentive Plan and a warrant to purchase 200,000 shares of our common stock at an exercise price of \$3.15 per share.

- (7) Dr. Howell is known to beneficially own an aggregate of 9,722 shares of our common stock, presently exercisable options for the purchase of 132,200 shares of our common stock pursuant to the 2005 Equity Incentive Plan and 9,500 shares of our common stock pursuant to the 1995 Stock Option Plan.
- (8) Dr. Nowotnik is known to beneficially own an aggregate of 5,116 shares of our common stock, presently exercisable options for the purchase of 359,286 shares of our common stock pursuant to the 2005 Equity Incentive Plan and 30,000 shares of our common stock pursuant to the 1995 Stock Option Plan.
- (9) Mr. Jacobucci is known to beneficially own an aggregate of 77,075 shares of our common stock and presently exercisable options for the purchase of 69,375 shares of our common stock pursuant to the 2005 Equity Incentive Plan.
- (10) SCO Capital Partners LLC, SCO Capital Partner LP, Beach Capital LLC and SCO Financial Group's address is 1325 Avenue of the Americas, 27<sup>th</sup> Floor, New York, NY 10019. SCO Capital Partners LLC and affiliates (SCO Capital Partners LP, Beach Capital LLC and SCO Financial Group) are known to beneficially own an aggregate of 3,481,805 shares of our common stock, warrants to purchase an aggregate of 6,053,287 shares of our common stock and 14,642,278 shares of common stock issuable upon conversion of Series A Cumulative Convertible Preferred Stock. Each of Mr. Rouhandeh and Mr. Davis, directors of Access and Mr. Rouhandeh and Mr. Davis are executives of SCO Capital Partners LLC and disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein.
- (11) Ayer Capital Partners Master Fund, LP's address is 230, California Street, Suite 600, San Francisco, CA 94111. Ayer Capital Partners Master Fund has a restriction on exercise of the warrants they own such that their maximum beneficial ownership in us is 9.9%.
- (12) Larry N. Feinberg is a partner in Oracle Partners, L.P. His address is c/o Oracle Partners, L.P., 200 Greenwich Avenue, 3<sup>rd</sup> Floor, Greenwich, CT 06830. Oracle Partners, L.P. and affiliates (Oracle Institutional Partners, L.P., Oracle Investment Management, Inc., Sam Oracle Fund, Inc. and Mr. Feinberg) are known to beneficially own an aggregate of 493,593 shares of our common stock, warrants to purchase an aggregate of 728,850 shares of our common stock and Series A Cumulative Convertible Preferred Stock which may be converted into an aggregate of 3,015,931 shares of our common stock.
- (13) Lake End Capital LLC's address is 33 Tall Oaks Drive, Summit, NJ 07901. Lake End Capital LLC is known to beneficially own an aggregate of 335,575 shares of our common stock, warrants to purchase an aggregate of 724,026 shares of our common stock and 1,640,829 shares of common stock issuable to them upon conversion of Series A Cumulative Convertible Preferred Stock.
- (14) Does not include shares held by SCO Financial Group LLC and affiliates.

## TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS

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.

In the event SCO Capital Partners LLC (SCO) and its affiliates were to convert all of their shares of Series A Preferred Stock and exercise all of their warrants, they would own approximately 48.2% of the voting securities of Access. During 2011 and 2010, SCO and affiliates incurred \$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 Director, has served as a consultant and Senior Director, Oncology Clinical Research & Development, since August 2007. Dr. Cvitkovic receives 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. Dr. Cvitkovic's payments for consulting services and expense reimbursements are as follows:

<u>Year</u>	<u>Consulting Fees</u>	<u>Expense Reimbursement</u>
2011	\$ 145,000	\$ 14,000
2010	\$ 132,000	\$ -

Mark J. Ahn, Ph.D., a Director, received payments for consulting services and reimbursement of direct expenses for scientific consulting in 2010. Dr. Ahn'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>
2010	\$ 5,000	\$ 4,000	\$ 23,000

On October 12, 2000, the Board of Directors authorized a Restricted Stock Purchase Program. Under the program, the Company's executive officers and corporate secretary were given the opportunity to purchase shares of common stock in an individually designated amount per participant determined by the Compensation Committee of the Board of Directors. A total of 38,000 shares were purchased under the program by four eligible participants at \$27.50 per share, the fair market value of the common stock on October 12, 2000, for an aggregate consideration of \$1,045,000. The purchase price was paid through the participants' delivery of a 50%-recourse promissory note payable to the Company for three executive officer participants and a full-recourse promissory note payable to the Company for one participant. Each note bears interest at 5.87% compounded semi-annually and has a maximum term of ten years. The notes were secured by a pledge of the purchased shares to the Company. The Company originally recorded the notes receivable from participants in this program of \$1,045,000 as a reduction of equity in the Consolidated Balance Sheets. Interest on the notes was neither being collected nor accrued. The stock granted under the program was fully vested. The Board of Directors cancelled this program effective October 12, 2010. The stock and receivables were cancelled on October 12, 2010.

## MARKET FOR OUR COMMON STOCK

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

#### Market Information

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 2011 year-to-date and fiscal years 2010 and 2009. 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><u>Fiscal Year 2012 Year-to date</u></b>		
First quarter (through January 18, 2012)	\$ 1.40	\$ 1.33
<b><u>Fiscal Year Ended December 31, 2011</u></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
<b><u>Fiscal Year Ended December 31, 2010</u></b>		
First quarter	\$ 3.29	\$ 2.44
Second quarter	2.80	1.96
Third quarter	2.20	1.80
Fourth quarter	3.29	2.15

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

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

## **Holders**

The number of record holders of our common stock at January 18, 2012 was approximately 7,000. On January 18, 2012, the closing price for the common stock as quoted on the OTCBB was \$1.38. There were 23,897,870 shares of common stock outstanding at January 18, 2012.

There were 2,938,3617 shares of Series A Cumulative Convertible Preferred Stock convertible into 20,264,551 shares of Common Stock at January 18, 2012.

## **Options and Warrants**

There are 16,065,611 outstanding warrants and 2,319,284 outstanding options to purchase our common equity as of January 18, 2012.

## **Shares Eligible for Future Sales**

Access has issued 23,897,870 shares of its common stock as of January 18, 2012. Of these shares, all shares are unrestricted and held by non-affiliates, and are freely tradable without restriction under the Securities Act. These shares will be eligible for sale in the public market, subject to certain volume limitations and the expiration of applicable holding periods under Rule 144 under the Securities Act. In general, under Rule 144 as currently in effect, a person (or persons whose shares are aggregated) who has beneficially owned restricted shares for at least one year (including the holding period of any prior owner or affiliate) would be entitled to sell within any three-month period a number of shares that does not exceed the greater of one percent (1%) of the number of shares of common stock then outstanding or (2) the average weekly trading volume of the common stock during the four calendar weeks preceding the filing of a Form 144 with respect to such sale. Sales under Rule 144 are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us. Under Rule 144(k), a person who is not deemed to have been an affiliate of Access at any time during the three months preceding a sale, and who has beneficially owned the shares proposed to be sold for at least two years (including the holding period of any prior owner except an affiliate), is entitled to sell such shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144.

## **Dividend Policy**

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends in the foreseeable future on our common stock. The payment of dividends on common stock, if any, in the future is within the discretion of our Board of Directors and will depend on its 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 its business.

The holders of Series A Cumulative Convertible Preferred Stock are entitled to receive dividends of 6% per annum on their shares Series A Cumulative Convertible Preferred Stock. The dividends are payable by us semi-annually and may be paid by us either in cash, or if certain conditions are met, at our option, in shares of our common stock. To be eligible to pay dividends in shares of common stock, among other things, there must be in place a registration statement pursuant to which the holders of the Series A Cumulative Convertible Preferred Stock are permitted to utilize the prospectus thereunder to resell all of the shares of common stock issuable in relation to the Series A Cumulative Convertible Preferred Stock.

## Equity Compensation Plan Information

The following table sets forth information as of January 18, 2012 about shares of common stock outstanding and available for issuance under our existing equity compensation plans.

<u>Plan Category</u>	<b>Number of securities to be issued upon exercise of outstanding options</b>	<b>Weighted-average exercise price of outstanding options</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</b>
	<u>warrants and rights</u>	<u>warrants and rights</u>	<u>(a)</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders:			
2005 Equity Incentive Plan	2,261,784	\$ 2.26	1,797,095
1995 Stock Awards Plan	57,500	16.58	-
Equity compensation plans not approved by security holders:			
2007 Special Stock Option Plan	-	-	450,000
<b>Total</b>	<b>2,319,284</b>	<b>\$ 2.53</b>	<b>2,247,095</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 of which 100,000 have been issued. The purpose of the Plan is to encourage ownership of common stock by employees, consultants, advisors and directors 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. The options in the Plan granted to date expired March 12, 2010.

For a description of our equity incentive plans, see Footnote 11 to our Consolidated Financial Statements for the fiscal year ended December 31, 2010.



## DESCRIPTION OF SECURITIES

Access' certificate of incorporation authorizes the issuance of 100,000,000 shares of its common stock, \$.01 par value per share, and 2,000,000 shares of preferred stock, \$.01 par value per share, which may be issued in one or more series. Currently, 4,000 shares of preferred stock are designated as Series A Cumulative Convertible Preferred Stock and 300,000 are designated as Series A Junior Participating Preferred Stock. As of January 18, 2012 there were 23,897,870 shares of Access' common stock outstanding and held of record by approximately 7,000 stockholders, and there were 2,938,3617 shares of its Series A Cumulative Convertible Preferred Stock outstanding convertible into 20,264,551 shares of common stock.

### Common Stock

Holder of Access' common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and have the right to vote cumulatively for the election of directors. This means that in the voting at Access' annual meeting, each stockholder or his proxy, may multiply the number of his shares by the number of directors to be elected then cast the resulting total number of votes for a single nominee, or distribute such votes on the ballot among the nominees as desired. Holders of Access' common stock are entitled to receive ratably such dividends, if any, as may be declared by Access' Board of Directors out of funds legally available therefor, subject to any preferential dividend rights for Access' outstanding preferred stock. Upon Access' liquidation, dissolution or winding up, the holders of Access' common stock are entitled to receive ratably Access' net assets available after the payment of all debts and other liabilities and subject to the prior rights of any of Access' outstanding preferred stock. Holders of Access' common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of Access' common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Access' preferred stock which Access may designate and issue in the future.

### Preferred Stock

Access' Board of Directors is authorized, subject to certain limitations prescribed by law, without further stockholder approval, to issue from time to time up to an aggregate of 2,000,000 shares of preferred stock in one or more series and to fix or alter the designations, preferences, rights and any qualifications, limitations or restrictions of the shares of each such series thereof, including the dividend rights, dividend rates, conversion rights, voting rights and terms of redemption of shares constituting any series or designations of such series. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change of control. The fact that Access' board of directors has the right to issue preferred stock without stockholder approval allowed Access to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by Access' board of directors.

Access' Board of Directors has designated 4,000 shares of preferred stock as Series A Cumulative Convertible Preferred Stock. The shares of Series A Cumulative Convertible Preferred are convertible at the option of the holder into shares of our common stock at a conversion price of \$1.45 per share of common stock.

The Series A Cumulative Convertible Preferred Stock is entitled to a liquidation preference equal to \$10,000 per share and is entitled to a dividend of 6% per annum, payable semi-annually in cash or if certain conditions are met, in common stock, at the option of the Company at time of payment. Our ability to pay dividends in shares of common stock is limited by among other things a requirement that (i) there is an effective registration statement on the shares of common stock, issuable to the holders of Series A Cumulative Convertible Preferred Stock, in the 20 day period immediately prior to such dividend or (ii) that such shares of common stock referred to in (i) may be sold without restriction pursuant to Rule 144(k) during the 20 day period immediately prior to such dividend.

The Company has the right, but not the obligation, to force conversion of all, and not less than all, of the outstanding Series A Cumulative Convertible Preferred Stock into common stock (i) as long as the closing price of our common stock exceeds \$7.00 for at least 20 of the 30 consecutive trading days immediately prior to the conversion and the average daily trading volume is greater than 100,000 shares per day for at least 20 of the 30 consecutive trading days immediately prior to such conversion, in each case, immediately prior to the date on which we give notice of such conversion or (ii) if we close a sale of common stock in which the aggregate proceeds are equal to or greater than \$10,000,000. Our 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 conversion price of the Series A Cumulative Convertible Preferred Stock is subject to a price adjustment upon the issuance of additional shares of common stock for a price below \$1.45 per share and equitable adjustment for stock splits, dividends, combinations, reorganizations and the like.

The Series A Cumulative Convertible Preferred Stock will vote together with the common stock on an as-if-converted basis.

Holders of Series A Cumulative Convertible Preferred Stock are entitled to purchase their pro rata share of additional stock issuances in certain future financings.

### **Warrants**

As of January 18, 2012, warrants for the issuance of 16,055,611 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of \$2.08 per share, all of which are exercisable through various dates expiring between February 16, 2012 and November 30, 2016. Outstanding warrants to acquire 3,895,047 shares of our common stock include a price protection mechanism in which the exercise price of these warrants will automatically be lowered in the event we issue shares of our common stock for a price less than \$1.45 per share.

The descriptions of the warrants are only a summary and are qualified in their entirety by the provisions of the forms of the warrant.

### **Transfer Agent and Registrar**

The transfer agent and registrar of our common stock is American Stock Transfer & Trust Company, New York, New York.

### **Delaware Law and Certain Charter and By-Law Provisions**

#### *Certain anti-takeover provisions.*

We are subject to the provisions of Section 203 of the General Corporation Law of Delaware. Section 203 prohibits certain publicly held Delaware corporations from engaging in a "business combination" with an "interested stockholder," for a period of three years after the date of the transaction in which the person became an "interested stockholder", unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an "interested stockholder" is a person or entity who, together with affiliates and associates, owns (or within the preceding three years, did own) 15% or more of the corporation's voting stock. The statute contains provisions enabling a corporation to avoid the statute's restrictions if the stockholders holding a majority of the corporation's voting stock approve our Certificate of Incorporation provides that our directors shall be divided into three classes, with the terms of each class to expire on different years.

In addition, our Certificate of Incorporation, in order to combat "greenmail," provides in general that any direct or indirect purchase by us of any of our voting stock or rights to acquire voting stock known to be beneficially owned by any person or group which holds more than five percent of a class of our voting stock and which has owned the securities being purchased for less than two years must be approved by the affirmative vote of at least two-thirds of the votes entitled to be cast by the holders of voting stock, subject to certain exceptions. The prohibition of "greenmail" may tend to discourage or foreclose certain acquisitions of our securities which might temporarily increase the price of our securities. Discouraging the acquisition of a large block of our securities by an outside party may also have a potential negative effect on takeovers. Parties seeking control of us through large acquisitions of its securities will not be able to resort to

"greenmail" should their bid fail, thus making such a bid less attractive to persons seeking to initiate a takeover effort.

### **Elimination of Monetary Liability for Officers and Directors**

Our Certificate of Incorporation incorporates certain provisions permitted under the General Corporation Law of Delaware relating to the liability of directors. The provisions eliminate a director's liability for monetary damages for a breach of fiduciary duty, including gross negligence, except in circumstances involving certain wrongful acts, such as the breach of director's duty of loyalty or acts or omissions, which involve intentional misconduct or a knowing violation of law. These provisions do not eliminate a director's duty of care. Moreover, these provisions do not apply to claims against a Director for certain violations of law, including knowing violations of federal securities law. Our Certificate of Incorporation also contains provisions to indemnify the directors, officers, employees or other agents to the fullest extent permitted by the General Corporation Law of Delaware. We believe that these provisions will assist us in attracting and retaining qualified individual to serve as directors.

### **Indemnification of Officers and Directors**

Our Certificate of Incorporation also contains provisions to indemnify the directors, officers, employees or other agents to the fullest extent permitted by the General Corporation Law of Delaware. These provisions may have the practical effect in certain cases of eliminating the ability of shareholders to collect monetary damages from directors. We believe that these provisions will assist us in attracting or retaining qualified individuals to serve as our directors.

### **Disclosure of Commission Position on Indemnification For Securities Act Liabilities**

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, the Registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

### **EXPERTS**

The consolidated financial statements of Access for the years ended December 31, 2010 and 2009 included in this prospectus, and included in the Registration Statement, were audited by Whitley Penn LLP, an independent registered public accounting firm, as stated in their report appearing with the consolidated financial statements herein and incorporated in this Registration Statement, and are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The independent registered public accounting firm named above has no interest in the prospectus.

### **LEGAL MATTERS**

Bingham McCutchen LLP will pass upon the validity of the securities offered hereby. Several partners and attorneys of Bingham McCutchen LLP are also shareholders of Access.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the Securities and Exchange Commission, Washington, D.C. 20549, under the Securities Act of 1933, a registration statement on Form S-1 relating to the shares of common stock offered hereby. This Prospectus does not contain all of the information set forth in the registration statement and the exhibits and schedules thereto. For further information with respect to our company and the shares we are offering by this Prospectus you should refer to the registration statement, including the exhibits and schedules thereto. You may inspect a copy of the registration statement without charge at the Public Reference Section of the Securities and Exchange Commission at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission. The Securities and Exchange Commission also maintains an Internet site that contains reports, proxy and information statements and other information regarding registrants that file electronically with the Securities and Exchange Commission. The Securities and Exchange Commission's World Wide Web address is <http://www.sec.gov>.

We file periodic reports, proxy statements and other information with the Securities and Exchange Commission in accordance with requirements of the Exchange Act. These periodic reports, proxy statements and other information are available for inspection and copying at the regional offices, public reference facilities and Internet site of the Securities and Exchange Commission referred to above. In addition, you may request a copy of any of our periodic reports filed with the Securities and Exchange Commission at no cost, by writing or telephoning us at the following address:

Investor Relations  
Access Pharmaceuticals, Inc.  
2600 Stemmons Freeway, Suite 176  
Dallas, Texas 75207  
(214) 905-5100

Information contained on our website is not a prospectus and does not constitute a part of this Prospectus.

You should rely only on the information contained in or incorporated by reference or provided in this Prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume the information in this Prospectus is accurate as of any date other than the date on the front of this Prospectus.

**FINANCIAL STATEMENTS**  
**ACCESS PHARMACEUTICALS, INC.**

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## 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, 2010 and 2009, 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, 2010 and 2009, 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.

As described in Note 9 to the consolidated financial statements, the Company adopted Emerging Issues Task Force Issue No. 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock* (Accounting Standards Codification Topic 815, *Derivatives and Hedging*) effective as of January 1, 2009.

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

/s/ WHITLEY PENN LLP

Dallas, Texas  
March 31, 2011

CONSOLIDATED BALANCE SHEETS

ASSETS	<u>December 31, 2010</u>	<u>December 31, 2009</u>
Current assets		
Cash and cash equivalents	\$ 7,033,000	\$ 607,000
Receivables	1,018,000	36,000
Prepaid expenses and other current assets	70,000	42,000
Total current assets	<u>8,121,000</u>	<u>685,000</u>
Property and equipment, net	32,000	50,000
Patents, net	574,000	787,000
Other assets	44,000	61,000
Total assets	<u><u>\$ 8,771,000</u></u>	<u><u>\$ 1,583,000</u></u>
 LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	\$ 2,984,000	\$ 4,094,000
Accrued expenses	857,000	857,000
Dividends payable	4,443,000	2,773,000
Accrued interest payable	126,000	563,000
Convertible debt, current portion	5,500,000	-
Current portion of deferred revenue	347,000	347,000
Total current liabilities	<u>14,257,000</u>	<u>8,634,000</u>
Derivative liability - warrants	5,087,000	9,708,000
Derivative liability - preferred stock	5,840,000	-
Long-term deferred revenue	4,382,000	4,730,000
Long-term convertible debt	-	5,500,000
Total liabilities	<u>29,566,000</u>	<u>28,572,000</u>
Commitments and contingencies		
Stockholders' deficit		
Convertible preferred stock - \$.01 par value; authorized 2,000,000 shares; 2,978.3617 issued at December 31, 2010; 2,992.3617 issued at December 31, 2009		
Common stock - \$.01 par value; authorized 100,000,000 shares; issued 19,115,010 at December 31, 2010; issued 13,171,545 at December 31, 2009	191,000	132,000
Additional paid-in capital	230,153,000	215,735,000
Notes receivable from stockholders	-	(1,045,000)
Treasury stock, at cost – 163 shares	(4,000)	(4,000)
Accumulated deficit	(251,135,000)	(241,807,000)
Total stockholders' deficit	<u>(20,795,000)</u>	<u>(26,989,000)</u>
Total liabilities and stockholders' deficit	<u><u>\$ 8,771,000</u></u>	<u><u>\$ 1,583,000</u></u>



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

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

	December 31,	
	2010	2009
Revenues		
License revenues	\$ 347,000	\$ 315,000
Sponsored research and development	58,000	-
Royalties	76,000	37,000
Total revenues	<u>481,000</u>	<u>352,000</u>
Expenses		
Research and development	3,349,000	2,657,000
Product costs	140,000	-
General and administrative	4,511,000	7,112,000
Depreciation and amortization	238,000	259,000
Total expenses	<u>8,238,000</u>	<u>10,028,000</u>
Loss from operations	(7,757,000)	(9,676,000)
Interest and miscellaneous income	2,046,000	29,000
Interest and other expense	(607,000)	(539,000)
Gain (loss) on change in fair value of derivative-warrants	4,621,000	(7,154,000)
Loss on change in fair value of derivative-preferred stock	(5,840,000)	-
	<u>220,000</u>	<u>(7,664,000)</u>
Net loss	(7,537,000)	(17,340,000)
Less preferred stock dividends	(1,791,000)	(1,886,000)
Net loss allocable to common stockholders	<u>\$ (9,328,000)</u>	<u>\$ (19,226,000)</u>
Basic and diluted loss per common share		
Net loss allocable to common stockholders	<u>\$ (0.60)</u>	<u>\$ (1.63)</u>
Weighted average basic and diluted common shares outstanding	<u>15,633,110</u>	<u>11,818,530</u>

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT**

					Additional paid-in	Notes receivable from stockholders	Treasury stock	Accumulated
Balance, December 31, 2008	9,467,000	\$95,000	3,242.8617	\$ -	\$225,753,000	\$(1,045,000)	\$(4,000)	\$(235,985,000)
Cumulative effect of a change in accounting principle (See Note 9)	-	-	-	-	(15,957,000)	-	-	13,404,000
Restricted common stock issued for services	687,000	8,000	-	-	2,199,000	-	-	-
Warrants issued for services	-	-	-	-	796,000	-	-	-
Common stock issued for cash exercise of options	250,000	2,000	-	-	177,000	-	-	-
Common stock issued for cashless warrant exercises	33,000	-	-	-	-	-	-	-
Preferred stock converted into common stock	836,000	9,000	(250.5000)	-	(9,000)	-	-	-
Common stock issued for preferred dividends	915,000	9,000	-	-	918,000	-	-	-
Stock option compensation expense	-	-	-	-	811,000	-	-	-
Common stock issued to MacroChem noteholders for notes and accrued interest	859,000	8,000	-	-	851,000	-	-	-
Common stock issued to former MacroChem executives	125,000	1,000	-	-	196,000	-	-	-
Preferred dividends	-	-	-	-	-	-	-	(1,886,000)
Net loss	-	-	-	-	-	-	-	(17,340,000)
Balance, December 31, 2009	13,172,000	132,000	2,992.3617	-	215,735,000	(1,045,000)	(4,000)	(241,807,000)
Restricted common stock issued for services	427,000	4,000	-	-	847,000	-	-	-
Warrants issued for services	-	-	-	-	74,000	-	-	-
Common stock issued for cash exercise of options	153,000	2,000	-	-	191,000	-	-	-
Common stock issued for cashless warrant exercises	42,000	-	-	-	-	-	-	-
Preferred stock converted into common stock	47,000	-	(14.0000)	-	-	-	-	-
Common stock issued for preferred dividends	127,000	1,000	-	-	287,000	-	-	-
Stock option compensation expense	-	-	-	-	1,015,000	-	-	-
Common stock issued \$3.00 share, net of costs	2,083,000	21,000	-	-	5,827,000	-	-	-
Common stock issued \$2.55 share, net of costs	3,102,000	31,000	-	-	7,222,000	-	-	-
Cancellation of notes receivable	(38,000)	-	-	-	(1,045,000)	1,045,000	-	-
Preferred dividends	-	-	-	-	-	-	-	(1,791,000)
Net loss	-	-	-	-	-	-	-	(7,537,000)
Balance, December 31, 2010	<u>19,115,000</u>	<u>\$191,000</u>	<u>2,978.3617</u>	<u>\$ -</u>	<u>\$ 230,153,000</u>	<u>\$ -</u>	<u>\$ (4,000)</u>	<u>\$ 251,135,000</u>

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



**Access Pharmaceuticals, Inc. and Subsidiaries**

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2010	2009
Cash flows from operating activities:		
Net loss	\$ (7,537,000)	\$ (17,340,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss (gain) on change in fair value of derivative-warrants	(4,621,000)	7,154,000
Loss on change in fair value of derivative-preferred stock	5,840,000	-
Gain on negotiated payables	(509,000)	-
Depreciation and amortization	238,000	259,000
Stock option compensation expense	1,015,000	811,000
Stock and warrants issued for services	925,000	3,200,000
Change in operating assets and liabilities:		
Receivables	(982,000)	111,000
Prepaid expenses and other current assets	(28,000)	133,000
Other assets	17,000	17,000
Accounts payable and accrued expenses	(601,000)	369,000
Dividends payable	168,000	(82,000)
Accrued interest payable	(437,000)	452,000
Deferred revenue	(348,000)	2,668,000
Net cash used in operating activities	(6,860,000)	(2,248,000)
Cash flows from investing activities:		
Capital expenditures	(7,000)	(2,000)
Proceeds from sale of asset	-	1,000
Net cash used in investing activities	(7,000)	(1,000)
Cash flows from financing activities:		
Proceeds from exercise of stock options	192,000	179,000
Proceeds from common stock issuances, net of costs	13,101,000	-
Net cash provided by financing activities	13,293,000	179,000
Net increase (decrease) in cash and cash equivalents	6,426,000	(2,070,000)
Cash and cash equivalents at beginning of year	607,000	2,677,000
Cash and cash equivalents at end of year	\$ 7,033,000	\$ 607,000
<i>Supplemental cash flow information:</i>		
<i>Cash paid for interest</i>	\$ 874,000	\$ 1,000
<i>Supplemental disclosure of noncash transactions</i>		
<i>Shares issued for payables, notes payable and accrued interest</i>	-	859,000
<i>Shares issued for dividends on preferred stock</i>	288,000	927,000
<i>Warrants issued for placement agent fees</i>	274,000	-
<i>Preferred stock dividends in dividends payable</i>	1,791,000	1,886,000

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



## Access Pharmaceuticals, Inc. and Subsidiaries

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Two years ended December 31, 2010

#### 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 since inception on February 24, 1988.

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

##### Principles of Consolidation

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

##### Use of Estimates

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

##### Segments

The Company operates in a single segment.

##### Cash and Cash Equivalents

We consider all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At December 31, 2010 and 2009, 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.

##### Property and Equipment

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

##### Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses include, but are not limited to, payroll and personnel expense, lab supplies, preclinical, development cost, clinical trial expense, outside manufacturing and consulting. The cost of materials and equipment or facilities that are acquired for research and development activities and that have alternative future uses are capitalized when acquired.





### Fair Value of Financial Instruments

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

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, 2010 and 2009, we did not recognize any interest or penalty expense related to income taxes. It is determined not to be reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 12 months. We are currently subject to a three year statute of limitations by major tax jurisdictions. We and our subsidiaries file income tax returns in the U.S. federal jurisdiction.

### Loss Per Share

We have presented basic loss per share, computed on the basis of the weighted average number of common shares outstanding during the year, and diluted loss per share, computed on the basis of the weighted average number of common shares and all dilutive potential common shares outstanding during the year. Potential common shares result from stock options, vesting of restricted stock grants, convertible notes, 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 25,784,976 and 21,658,171 were excluded from the loss per share computation for 2010 and 2009, respectively.

### Patents

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

Intangible assets consist of the following (in thousands):

	<u>December 31, 2010</u>		<u>December 31, 2009</u>	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated amortization
Amortizable intangible assets - Patents	\$ 2,624	\$ 2,050	\$ 2,624	\$ 1,837

Amortization expense related to intangible assets totaled \$213,000 and \$212,000 for the years ended December 31, 2010 and 2009, respectively. The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2010 is as follows (in thousands):

2011	\$	212
2012		82
2013		44
2014		44
2015		44
Thereafter		148
Total	\$	<u>574</u>

### Revenues

Our revenues are generated from licensing, research and development agreements and royalties. 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.

### Other Income

In 2010 we were awarded \$1,479,000 in grants from the Qualifying Therapeutic Discovery Project Grants from the United States government. As these are non-recurring in nature, we recorded them in Other Income. We received payment of \$540,000 in 2010 and recorded the remaining \$938,000 in receivables at December 31, 2010.

### 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 2010 and 2009, 640,000 stock options and 565,000 stock options, respectively, were granted under the 2005 Equity Incentive Plan. Assumptions for 2010 and 2009 are:

	<u>2010</u>	<u>2009</u>
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.	123%	115%
Risk-free interest rate assumption is based upon U.S. Treasury bond interest rates appropriate for the term of the our employee stock options.	2.32%	2.37%
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.	5.7 years	5.5 years

At December 31, 2010, 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 \$1,031,000. The weighted-average period over which the unearned stock-based compensation is expected to be recognized is approximately two 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, 2010 and 2009 which was allocated as follows (in thousands):

	Year ended December 31, 2010	Year ended December 31, 2009
Research and development	\$ 678	\$ 381
General and administrative	337	430
Stock-based compensation expense included in operating expense	<u>1,015</u>	<u>811</u>
Total stock-based compensation expense	1,015	811
Tax benefit	-	-
Stock-based compensation expense, net of tax	<u>\$ 1,015</u>	<u>\$ 811</u>

#### Recent Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (FASB) issued ASU 2010-17 (ASU 2010-17), "Revenue Recognition-Milestone Method (Topic 605): Milestone Method of Revenue Recognition." The amendments in this Update are effective on a prospective basis for milestones achieved in fiscal years, and interim periods within those years, beginning on or after June 15, 2010. Early adoption is permitted. If a vendor elects early adoption and the period of adoption is not the beginning of the entity's fiscal year, the entity should apply the amendments retrospectively from the beginning of the year of adoption. We will adopt this standard effective January 1, 2011. We do not expect the provisions of ASU 2010-17 to have a material effect on the financial position, results of operations or cash flows of us.

In December 2010, the FASB issued ASU 2010-27, *Fees Paid to the Federal Government by Pharmaceutical Manufacturers*. ASU 2010-27 specifies that the liability for our portion of the annual fee on the pharmaceutical manufacturing industry should be estimated and recorded in full upon the first qualifying sale with a corresponding deferred cost that is amortized to expense using a straight-line method of allocation unless another method better allocates the fee over the calendar year that it is payable. ASU 2010-27 is effective for calendar years beginning after December 31, 2010, when the fee initially becomes effective. ASU 2010-27 will not impact our consolidated financial position, results of operations or cash flows until the period in which we begin sales of our pharmaceutical products.

#### **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, 2010 and 2009.

Management believes that our current cash and expected license fees should fund our expected burn rate into the first quarter of 2012. We are a party to a \$5.5 million promissory note due on September 13, 2011. While our plan is to extend the due date of this note, if we are unable to do so we may not have sufficient capital to continue our operations. We will require additional funds to continue operations. These funds are expected to come from the future sales of equity and/or license agreements.

#### **NOTE 3 - RELATED PARTY TRANSACTIONS**

In the event SCO Capital Partners LLC (SCO) and its affiliates were to convert all of their shares of Series A Preferred Stock and exercise all of their warrants, they would own approximately 45.1% of the voting securities of Access. During 2010 and 2009, SCO and affiliates incurred \$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 Director, has served as a consultant and Senior Director, Oncology Clinical Research & Development, since August 2007. Dr. Cvitkovic receives payments for consulting expenses, office expenses and reimbursement of direct expenses. Dr. Cvitkovic also has received the following warrants and options for his consulting. In May 2009, Dr. Cvitkovic received options to purchase 75,000 shares of our Common Stock at \$1.38 with all options currently vested and can be exercised until January 4, 2012. In January 2008, Dr. Cvitkovic received warrants to purchase 200,000 shares of our Common Stock at \$3.15 per share that can be exercised until January 4, 2012. All of the warrants are currently vested. Dr. Cvitkovic's payments for consulting services and expense reimbursements are as follows:

Year	Consulting Fees	Office Expenses	Expense Reimbursement	Fair Value of exercisable Warrants
2010	\$ 132,000	\$ -	\$ -	\$ -
2009	\$ 132,000	\$ 18,000	\$ 10,000	\$ 86,000

Mark J. Ahn, Ph.D., a Director, received payments for consulting services and reimbursement of direct expenses for scientific consulting in 2010. Dr. Ahn's payments for consulting services and expense reimbursements are as follows:

Year	Consulting Fees	Expense Reimbursement	Fair Value of Restricted Stock
2010	\$ 5,000	\$ 4,000	\$ 23,000

See Note 10 for a discussion of our Restricted Stock Purchase Program.

#### NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:	December 31,	
	2010	2009
Laboratory equipment	\$ 788,000	\$ 786,000
Laboratory and building improvements	58,000	58,000
Furniture and equipment	56,000	567,000
	<u>902,000</u>	<u>1,411,000</u>
Less accumulated depreciation and amortization	870,000	1,361,000
Property and equipment, net	<u>\$ 32,000</u>	<u>\$ 50,000</u>

Depreciation and amortization on property and equipment was \$25,000 and \$47,000 for the years ended December 31, 2010 and 2009, respectively.

#### NOTE 5 - 401(k) PLAN

We have a tax-qualified employee savings and retirement plan (the 401(k) Plan) covering all our employees. Pursuant to the 401(k) Plan, employees may elect to reduce their current compensation by up to the statutorily prescribed annual limit (\$16,500 in 2010 and \$15,500 in 2009) 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 five months of 2009 and \$0 for the remainder of 2009 and 2010. The Company suspended matching on June 1, 2009 and through the twelve months ended December 31, 2010. 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 82 investment options. Company contributions under the 401(k) Plan were approximately \$0 in 2010 and \$16,000 in 2009.

## NOTE 6 – DEBT

\$5,500,000 due on September 13, 2011. The unsecured convertible note bears interest at 7.7% per annum with \$423,500 of interest due annually on September 13<sup>th</sup>. This note has a fixed conversion price of \$27.50 per share of common stock and may be converted by the note holder or us under certain circumstances as defined in the note. If the notes are not converted we will have to repay the notes on the due date.

## NOTE 7 – COMMITMENTS AND CONTINGENCIES

### Operating Leases

At December 31, 2010, we had commitments under non-cancelable operating leases for office and research and development facilities until December 31, 2011 totaling \$77,000. Rent expense for the years ended December 31, 2010 and 2009 was \$110,000 and \$111,000, respectively. We also have one non-cancelable operating lease – for a copier with future obligations totaling approximately \$10,000 ending in 2011.

### Legal

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

## NOTE 8 - FAIR VALUE MEASUREMENTS

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

Effective January 1, 2008, we adopted fair value measurement guidance issued by the FASB related to financial assets and liabilities which define 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.
- 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, 2010 and December 31, 2009 are summarized below:

(in thousands)

Description	As of December 31, 2010	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability-					
warrants	\$ 5,087	\$ -	\$ 5,087	\$ -	\$ 4,621
preferred stock	\$ 5,840	\$ -	\$ -	\$ 5,840	\$ (5,840)

(in thousands)

Description	As of December 31, 2009	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability-					
warrants	\$ 9,708	\$ -	\$ 9,708	\$ -	\$ (7,154)
preferred stock	\$ -	\$ -	\$ -	\$ -	\$ -

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 expected future volatility of the price of the Company's stock. In estimating the fair value at December 31, 2010, 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

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, see 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 December 14, 2010, we issued common stock in a registered direct offering at \$2.55 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 \$2.55 per share. The Series A Preferred Stock at December 31, 2010 was converted into 11,679,836 shares of common stock, an increase of 1,751,970 shares of common stock.





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 and re-priced from \$3.00 to \$2.55 due to the offering on December 14, 2010.

#### November 7, 2007 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 December 14, 2010, the conversion price changed to \$2.55 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 December 14, 2010 the conversion price changed to \$2.55 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.

#### Change In Accounting Principle

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, asset 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. FASB ASC 815 provides for transition guidance whereby a cumulative effect of a change in accounting principle should be recognized as an adjustment to retained earnings and other impacted balance sheet items as of January 1, 2009. The cumulative-effect adjustment is the difference between the amounts recognized prior to adoption and amounts recognized at adoption assuming this guidance had been applied from the issuance date of the preferred stock and warrants.

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 is \$5,840,000. 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. Additionally, we reclassified \$15,957,000 of previously recorded beneficial conversion features recorded under the previous accounting that related to the preferred stock and warrants. The impact of adoption was a decrease in Additional paid-in capital of \$15,957,000, a decrease in accumulated deficit of \$13,404,000 and an increase in derivative liability of \$2,553,000.

The resulting accounting led to derivative warrant liability of \$2,553,000 as of January 1, 2009 and \$9,708,000 as of December 31, 2009. We recorded derivative expense of \$7,154,000 for the year ended December 31, 2009 and \$4,621,000 gain for the year ended December 31, 2010.

The fair value of the derivative warrant liability was calculated using the Black-Scholes option pricing model. The assumptions that were used to calculate fair value were as follows.

	<u>January 1, 2009</u>	<u>December 31, 2009</u>
Risk-free interest rate	1.55%	2.69%
Expected volatility	116.31%	117.43%
Expected life (in years)	4.88	3.88
Dividend yield	0.00%	0.00%

As noted above, we were required to adopt this guidance effective January 1, 2009, however we did not apply this guidance to its 2009 Form 10-Q's as required and instead recorded the adoption impact and current year activity in the fourth quarter. The impact, if recorded in the appropriate quarterly period would have been an increase in expense and derivative liability of \$2,104,000, \$2,036,000 and \$1,929,000 for the three months ended March 31, June 30, and September 30, 2009, respectively. Additionally, our Form 10-Q's for 2009 do not reflect the cumulative impact of the change in accounting principle which resulted in a decrease in additional paid-in capital of \$15,957,000, a decrease in accumulated deficit of \$13,404,000 and an increase in derivative liability of \$2,553,000 on January 1, 2009.

### 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, 2010 and December 31, 2009. 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

Preferred stock dividends of \$4,443,000 were accrued at December 31, 2010, plus interest. Dividends are payable semi-annually in either cash or common stock.

## **NOTE 10 – STOCKHOLDERS' EQUITY**

### Restricted Stock Purchase Program

On October 12, 2000, the Board of Directors authorized a Restricted Stock Purchase Program. Under the program, the Company's executive officers and corporate secretary were given the opportunity to purchase shares of common stock in an individually designated amount per participant determined by the Compensation Committee of the Board of Directors. A total of 38,000 shares were purchased under the program by four eligible participants at \$27.50 per share, the fair market value of the common stock on October 12, 2000, for an aggregate consideration of \$1,045,000. The purchase price was paid through the participants' delivery of a 50%-recourse promissory note payable to the Company for three executive officer participants and a full-recourse promissory note payable to the Company for one participant. Each note bears interest at 5.87% compounded semi-annually and has a maximum term of ten years. The notes were secured by a pledge of the purchased shares to the Company. The Company originally recorded the notes receivable from participants in this program of \$1,045,000 as a reduction of equity in the Consolidated Balance Sheets. Interest on the notes was neither being collected nor accrued. The stock granted under the program was fully vested. The Board of Directors cancelled this program effective October 12, 2010. The stock and receivables were cancelled on October 12, 2010.

### Warrants

There were warrants to purchase a total of 12,060,907 shares of common stock outstanding at December 31, 2010. All warrants were exercisable at December 31, 2010 except for warrants to acquire 188,000 shares of common stock. 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>
2010 December registered direct offering (a)	930,664	\$ 3.06	12/14/15
2010 January registered direct offering (b)	1,041,432	3.00	1/26/15
2010 January placement agent warrants (b)	125,109	3.75	1/26/15
2010 investor relations advisor (c)	169,000	2.16	10/1/13
2010 investor relations advisor (d)	55,000	2.63	10/14/13
2009 investor relations advisor (e)	30,000	3.45	9/15/12
2009 business consultant (f)	150,000	2.07	7/23/14
2009 investor relations advisor (g)	50,000	6.00	8/27/12
2008 preferred stock offering (h)	499,584	2.55	2/24/14
2008 Somanta accounts payable (i)	246,753	3.50	1/4/14
2008 warrants assumed on acquisition (j)	191,668	18.55-23.19	1/31/12
2008 investor relations advisor (k)	50,000	3.15	1/3/13
2008 investor relations advisor (l)	40,000	3.00	9/1/13
2008 scientific consultant (m)	200,000	3.15	1/4/12
2007 preferred stock offering (n)	3,649,880	2.55	11/10/13
2006 convertible note (o)	3,818,180	1.32	2/16/12
2006 convertible note (o)	386,364	1.32	10/24/12

2006 convertible note (o)	377,273	1.32	12/6/12
2006 investor relations advisor (p)	<u>50,000</u>	2.70	12/27/11
Total	<u><u>12,060,907</u></u>		

- a) 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 five years from the date of issue.
- b) 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 five years from the date of issue.

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 five years from the date of issue. The fair value of the warrants was \$2.19 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 2.38%, expected volatility 119% and a term of 5 years.

- c) 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 at any time until October 1, 2013, for investor relations consulting services rendered in 2010 and 2011. The expense recorded for the year ended December 31, 2010 was \$55,000. Our common stock did not reach a target price by February 28, 2011 and according to the agreement 25,000 warrants expired.
- d) 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. The warrants did not vest and expired January 31, 2011. No expense was recorded.
- e) During 2009, an investor relations advisor received warrants to purchase 30,000 shares of common stock at an exercise price of \$3.45 per share at any time until September 15, 2012, for investor relations consulting services rendered from October 2009 through March 2010. As of December 31, 2010 all 30,000 warrants were exercisable. The expense recorded for the years ended December 31, 2010 and 2009 was \$19,000 and \$24,000, respectively.
- f) 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, 2009. The remaining 90,000 warrants expired July 23, 2010 because our stock did not reach specified trading prices. The expense recorded for the years ended December 31, 2009 was \$238,000.
- g) During 2009, an investor relations advisor received warrants to purchase 50,000 shares of common stock at an exercise price of \$6.00 per share at any time until August 27, 2012, for investor relations consulting services rendered in 2009. All 50,000 of the warrants were exercisable at December 31, 2009. The fair value of the warrants was \$2.04 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 1.58%, expected volatility 119% and a term of 3 years. The expense recorded for the year ended December 31, 2009 was \$102,000.
- h) In connection with the preferred stock offering in February 2008, warrants to purchase a total of 499,584 shares of common stock were issued. All of the warrants are exercisable immediately and expire six years from date of issue. The fair value of the warrants was \$2.29 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.75%, expected volatility 110% and a term of 6 years. The exercise price of \$3.50 was decreased to \$3.00 after the January 2010 placement and to \$2.55 after the December 2010 placement.
- i) 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.

- j) We assumed two warrants in the Somanta acquisition:  
 -Warrant#1 – 31,943 shares of our common stock at \$18.55 per share and expires January 31, 2012.  
 -Warrant #2 – 159,725 shares of our common stock at \$23.19 per share and expires January 31, 2012.
- k) 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. 25,000 of the warrants were exercisable on July 3, 2008 and 25,000 of the warrants will be exercisable January 3, 2009.
- l) During 2008, an investor relations advisor received warrants to purchase 40,000 shares of common stock at an exercise price of \$3.00 per share at any time until September 1, 2013, for investor relations consulting services. All of the warrants are exercisable. The fair value of the warrants was \$2.61 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.37%, expected volatility 132% and a term of 5 years.
- m) During 2008, a director who is also a scientific advisor received warrants to purchase 200,000 shares of common stock at an exercise price of \$3.15 per share at any time until January 4, 2012, for scientific consulting services rendered in 2008. The warrants vest over two years in 50,000 share blocks with vesting on July 4, 2008, January 4, 2009, July 4, 2009 and the remaining shares on January 4, 2010.
- n) 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 and to \$2.55 after the December 2010 placement.
- o) In connection with the convertible note offerings in 2006, warrants to purchase a total of 4,581,817 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.
- p) During 2006, an investor relations advisor received warrants to purchase 50,000 shares of common stock at an exercise price of \$2.70 per share at any time from December 27, 2006 until December 27, 2011, for investor relations consulting services rendered in 2007. All of the warrants are exercisable.

#### 2001 Restricted Stock Plan

We have a restricted stock plan, the 2001 Restricted Stock Plan, as amended, under which 80,000 shares of our authorized but unissued common stock were reserved for issuance to certain employees, directors, consultants and advisors. The restricted stock granted under the plan generally vests, 25% two years after the grant date with additional 25% vesting every anniversary date. All stock is vested after five years. At December 31, 2010 there were 27,182 shares issued and 52,818 shares available for grant under the 2001 Restricted Stock Plan. All the issued shares are vested.

#### 2010 Registered Direct Offerings – New Common Stock and Warrants

On January 26, 2010, we completed the sale of 2,083,000 shares of our common stock and warrants to purchase 1,041,000 shares of our common stock at an exercise price of \$3.00 per share for an aggregate purchase price of \$6.3 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 a total of 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 five years from the date of issue. The fair value of the warrants was \$2.19 per share on the date of grant using the Black-Scholes pricing model with the following assumptions: expected yield 0.0%, risk-free interest rate 2.38%, expected volatility 119% and an expected term of 5 years.

On December 14, 2010, we completed the sale of 3,102,000 shares of our common stock at \$2.55 per share and warrants to purchase 931,000 shares of our common stock at an exercise price of \$3.06 per share for an aggregate purchase price of \$7.9 million. Proceeds, net of cash issuance costs from the sale, were \$7.3 million.

## 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 2010: dividend yield of 0%; volatility of 123%; risk-free interest rate of 2.32%; and expected lives of 5.7 years. The weighted average fair value of options granted was \$2.57 per share during 2010. The assumptions for grants in fiscal 2009 were: dividend yield of 0%; volatility of 115%; risk-free interest rate of 2.37%; and expected lives of 5.5 years.

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

	<u>Options</u>	Weighted- average exercise <u>price</u>
Outstanding options at January 1, 2009	1,136,820	1.90
Granted, fair value of \$ 1.31 per share	565,000	1.38
Exercised	(249,916)	0.73
Expired	<u>(16,667)</u>	3.00
Outstanding options at December 31, 2009	1,435,237	1.99
Granted, fair value of \$ 2.23 per share	640,000	2.57
Exercised	(153,051)	1.26
Expired	<u>(173,453)</u>	3.51
Outstanding options at December 31, 2010	<u>1,748,733</u>	2.13
Exercisable at December 31, 2010	1,249,580	1.88

The intrinsic value of options under this plan related to the outstanding and exercisable options were \$1,063,000 and \$1,059,000 at December 31, 2010, respectively. The intrinsic value of options under this plan related to the outstanding and exercisable options were \$2,112,000 and \$2,050,000, respectively at December 31, 2009.

The total intrinsic value of options exercised during 2010 was \$187,000 and during 2009 was \$642,000.

Further information regarding options outstanding under the 2005 Equity Incentive Plan at December 31, 2010 is summarized below:





Range of exercise prices	Number of options outstanding	Weighted average		Number of options exercisable	Weighted average	
		Remaining life in years	Exercise price		Remaining life in years	Exercise price
\$0.63 - 0.85	387,500	5.6	\$0.64	387,500	5.6	\$0.64
\$1.38	306,949	8.4	\$1.38	306,949	8.4	\$1.38
\$2.45-2.79	640,000	9.3	\$2.57	272,500	9.4	\$2.46
\$3.00 - 7.23	414,284	7.3	\$3.39	282,631	7.2	\$3.57
	<u>1,748,733</u>			<u>1,249,580</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, 2010, 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, 2010, there were no additional shares available for grant under the 1995 Stock Awards Plan. A total of 59,500 options were outstanding under this plan at December 31, 2010.

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>	Weighted-average exercise price
Outstanding options at January 1, 2009	118,000	\$ 15.14
Expired	<u>(15,000)</u>	10.00
Outstanding options at December 31, 2009	103,000	15.89
Expired	<u>(43,500)</u>	14.65
Outstanding options at December 31, 2010	<u>59,500</u>	16.80
Exercisable at December 31, 2010	59,500	16.80

There was no intrinsic value related to outstanding or exercisable options under this plan at December 31, 2010 or 2009.

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2010 is summarized below:

Range of exercise prices	Number of Options outstanding	Weighted average		Number of Options exercisable	Weighted-average	
		Remaining life in years	Exercise price		Remaining life in years	Exercise price
\$10.10 - 12.40	29,000	3.4	\$11.09	29,000	3.4	\$11.09
\$14.05 - 18.65	18,000	1.2	\$18.14	18,000	1.2	\$18.14
\$23.05 - 29.25	12,500	2.8	\$28.11	12,500	2.8	\$28.10
	<u>59,500</u>			<u>59,500</u>		

## NOTE 12 - INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

	2010	2009
Income taxes at U.S. statutory rate	\$ (3,172,000)	\$ (6,537,000)
Change in valuation allowance	2,211,000	5,182,000
Benefit of foreign losses not recognized	30,000	57,000
Expenses not deductible	109,000	623,000
Expiration of net operating loss and general business credit carryforwards, net of revisions	822,000	675,000
Total tax expense	\$ -	\$ -

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:

	December 31,	
	2010	2009
Deferred tax assets		
Net operating loss carryforwards	\$ 62,760,000	\$ 62,358,000
General business credit carryforwards	2,315,000	2,371,000
State credits	3,101,000	3,126,000
Property and equipment	49,000	51,000
Stock options	1,118,000	773,000
Derivatives	3,715,000	2,432,000
Deferred revenue	1,622,000	748,000
Intangible assets	409,000	383,000
Accrued interest	253,000	-
Other	270,000	270,000
Gross deferred tax assets	75,612,000	72,512,000
Valuation allowance	(75,612,000)	(72,512,000)
Net deferred taxes	\$ -	\$ -

At December 31, 2010, we had approximately \$184,588,000 of net operating loss carryforwards and approximately \$2,315,000 of general business credit carryforwards. These carryforwards expire as follows:

	Net operating loss carryforwards	General business credit carryforwards
2011	\$ 4,488,000	\$ 13,000
2012	4,212,000	77,000
2013	-	-
2014	-	-
2015	-	-

Thereafter	<u>175,888,000</u>	<u>2,225,000</u>
	\$ <u>184,588,000</u>	\$ <u>2,315,000</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, 2010 and 2009, we did not recognize any interest or penalty expense related to income taxes. It is determined not to be reasonably likely for the amounts of unrecognized tax benefits to significantly increase or decrease within the next 12 months. We are currently subject to a three year statute of limitations by major tax jurisdictions. We and our subsidiaries file income tax returns in the U.S. federal jurisdiction.

### **NOTE 13 – MACROCHEM CORPORATION ACQUISITION**

On February 25, 2009, we issued approximately 2,500,000 shares of our common stock in exchange for 100% of the outstanding stock and warrants of MacroChem Corporation (MacroChem). MacroChem's principal activities were to develop and seek to commercialize pharmaceutical products using its proprietary drug delivery technologies. Its portfolio of proprietary product candidates was based on its drug delivery technologies: Soft Enhancement of Percutaneous Absorption (SEPA), MacroDerm and DermaPass. Its SEPA topical drug delivery technology enhances the efficiency and rate of diffusion of drugs into and through the skin. MacroChem had two clinical stage investigational new drugs: EcoNail, for the treatment of fungal infections of the nails and Pexiganan, for the treatment of mild diabetic foot infection (DFI).

Prior to our acquisition of MacroChem, SCO, an investment company, held a majority of Access' and MacroChem's voting stock. Specifically, SCO owned 53% of the voting stock of Access and 63% of the voting stock of MacroChem. A non-controlling interest of 37% existed at the merger date of MacroChem. In addition, certain members of SCO's management serve on the board of directors of both Access and MacroChem. Based on these facts, Access and MacroChem were deemed under the common control of SCO. As the entities were deemed under common control, the acquisition was recorded similar to the pooling-of-interest method and the financial information for all periods presented reflects the financial statements of the combined companies in accordance with Financial Accounting Standards Board standards on business combinations for entities under common control.

Upon acquisition, all outstanding warrants and any other dilutive instruments in MacroChem's stock were cancelled. The in-the-money warrants were converted with the common stock. In addition to the merger, the noteholders of MacroChem agreed to exchange their notes and interest due on the notes in the total amount of \$859,000 for 859,000 restricted shares of the Access' common stock. The value of the shares issued was determined based on the carrying value of the debt, which was established to be the more readily determinable fair value.

In addition, we issued 125,000 shares of our common stock to former executives of MacroChem for the settlement of employment agreements.

In connection with the exchange of equity interests, \$106,000 in merger costs were expensed.

The income statement for all periods presented reflects the combined carrying amount of revenue and expenses. Following is a summary statement of combined operations for the year ended December 31, 2009:

	For the year ended December 31, 2009		
	Access Pharmaceuticals	MacroChem Corporation	Combined
Total revenues	\$ 352,000	\$ -	\$ 352,000
Expenses			
Research and development	2,645,000	12,000	2,657,000
General and administrative	6,932,000	180,000	7,112,000
Depreciation and amortization	<u>207,000</u>	<u>52,000</u>	<u>259,000</u>
Total expenses	<u>9,784,000</u>	<u>244,000</u>	<u>10,028,000</u>
Loss from operations	(9,432,000)	(244,000)	(9,676,000)
Interest and miscellaneous Income	29,000	-	29,000
Interest and other expense	(513,000)	(26,000)	(539,000)
Change in fair value of derivative	<u>(7,154,000)</u>	<u>-</u>	<u>(7,154,000)</u>
	<u>(7,638,000)</u>	<u>(26,000)</u>	<u>(7,664,000)</u>
Loss from operations	(17,070,000)	(270,000)	(17,340,000)
Less preferred stock Dividends	<u>(1,886,000)</u>	<u>-</u>	<u>(1,886,000)</u>
Net loss allocable to common stockholders	<u>\$ (18,956,000)</u>	<u>\$ (270,000)</u>	<u>\$ (19,226,000)</u>
Basic and diluted loss per common share			
Net loss allocable to common stockholders	-	-	\$ (1.63)
Weighted average basic and diluted common shares outstanding	-	-	11,818,530

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Balance Sheets

	September 30, 2011	December 31, 2010
ASSETS	(unaudited)	
Current assets		
Cash and cash equivalents	\$ 1,348,000	\$ 7,033,000
Receivables	119,000	1,018,000
Inventory	192,000	-
Prepaid expenses and other current assets	27,000	70,000
Total current assets	1,686,000	8,121,000
Property and equipment, net	55,000	32,000
Patents, net	415,000	574,000
Other assets	64,000	44,000
Total assets	\$ 2,220,000	\$ 8,771,000
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	\$ 1,629,000	\$ 2,984,000
Accrued expenses	857,000	857,000
Dividends payable	5,966,000	4,443,000
Accrued interest payable	30,000	126,000
Convertible debt, current portion	5,500,000	5,500,000
Current portion of deferred revenue	285,000	347,000
Total current liabilities	14,267,000	14,257,000
Derivative liability - warrants	1,775,000	5,087,000
Derivative liability - preferred stock	6,310,000	5,840,000
Long-term deferred revenue	3,335,000	4,382,000
Total liabilities	25,687,000	29,566,000
Commitments and contingencies		
Stockholders' deficit		
Convertible Series A preferred stock - \$.01 par value; authorized 2,000,000 shares; 2,958.3617 shares issued at September 30, 2011 and 2,978.3617 shares issued at December 31, 2010		
Common stock - \$.01 par value; authorized 100,000,000 shares; issued, 19,517,296 at September 30, 2011 and 19,115,010 at December 31, 2010	195,000	191,000
Additional paid-in capital	231,617,000	230,153,000
Treasury stock, at cost – 163 shares	(4,000)	(4,000)
Accumulated deficit	(255,275,000)	(251,135,000)
Total stockholders' deficit	(23,467,000)	(20,795,000)
Total liabilities and stockholders' deficit	\$ 2,220,000	\$ 8,771,000

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Operations  
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Revenues				
License revenues	\$ 936,000	\$ 107,000	\$ 1,110,000	\$ 281,000
Sponsored research and development	-	-	30,000	-
Royalties	23,000	20,000	64,000	53,000
Product sales	82,000	-	138,000	-
Total revenues	<u>1,041,000</u>	<u>127,000</u>	<u>1,342,000</u>	<u>334,000</u>
Expenses				
Research and development	1,063,000	1,199,000	3,243,000	2,718,000
Product costs	454,000	-	812,000	-
General and administrative	1,252,000	1,165,000	3,297,000	3,316,000
Depreciation and amortization	56,000	59,000	176,000	179,000
Total expenses	<u>2,825,000</u>	<u>2,423,000</u>	<u>7,528,000</u>	<u>6,213,000</u>
Loss from operations	(1,784,000)	(2,296,000)	(6,186,000)	(5,879,000)
Interest and miscellaneous income	1,283,000	38,000	1,291,000	554,000
Interest and other expense	(237,000)	(152,000)	(760,000)	(444,000)
Gain on change in fair value of derivative - warrants	1,138,000	146,000	3,312,000	6,384,000
Loss on change in fair value of derivative - preferred stock	(50,000)	(10,455,000)	(470,000)	(10,455,000)
	<u>2,134,000</u>	<u>(10,423,000)</u>	<u>3,373,000</u>	<u>(3,961,000)</u>
Net income (loss)	350,000	(12,719,000)	(2,813,000)	(9,840,000)
Less preferred stock dividends	447,000	452,000	1,327,000	1,340,000
Net loss allocable to common stockholders	<u>\$ (97,000)</u>	<u>\$ (13,171,000)</u>	<u>\$ (4,140,000)</u>	<u>\$ (11,180,000)</u>
Basic/diluted net loss per common share				
Net loss allocable to common stockholders	<u>\$ (0.00)</u>	<u>\$ (0.83)</u>	<u>\$ (0.21)</u>	<u>\$ (0.73)</u>
Weighted average basic and diluted common shares outstanding	<u>19,503,383</u>	<u>15,774,273</u>	<u>19,378,579</u>	<u>15,337,453</u>

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



**Access Pharmaceuticals, Inc. and Subsidiaries**  
Condensed Consolidated Statements of Stockholders' Deficit  
(unaudited)

	<u>Common Stock</u>		<u>Preferred Stock</u>		Additional paid-in capital	Treasury stock	Accumulated deficit
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance December 31, 2010	19,115,000	\$ 191,000	2,978.3617	\$ -	\$230,153,000	\$ (4,000)	\$(251,135,000)
Restricted common stock issued for services	21,000	-	-	-	50,000	-	-
Common stock issued for services	85,000	1,000	-	-	195,000	-	-
Preferred stock converted into common stock	78,000	1,000	(20.0000)	-	-	-	-
Common stock issued for preferred dividends	1,000	-	-	-	-	-	-
Stock option compensation expense	-	-	-	-	181,000	-	-
Preferred dividends	-	-	-	-	-	-	(438,000)
Net loss	-	-	-	-	-	-	(1,899,000)
Balance at March 31, 2011	19,300,000	\$ 193,000	2,958.3617	\$ -	\$230,579,000	\$ (4,000)	\$(253,472,000)
Restricted common stock issued for services	75,000	1,000	-	-	165,000	-	-
Common stock issued for services	21,000	-	-	-	46,000	-	-
Warrants issued for services	-	-	-	-	17,000	-	-
Stock option compensation expense	-	-	-	-	242,000	-	-
Preferred dividends	-	-	-	-	-	-	(442,000)
Net loss	-	-	-	-	-	-	(1,264,000)
Balance at June 30, 2011	19,396,000	\$ 194,000	2,958.3617	\$ -	\$231,049,000	\$ (4,000)	\$(255,178,000)
Restricted common stock issued for							

services	100,000	1,000	-	-	210,000	-	-
Common stock issued for services	21,000	-	-	-	14,000	-	-
Stock option compensation expense	-	-	-	-	344,000	-	-
Preferred dividends	-	-	-	-	-	-	(447,000)
Net income	-	-	-	-	-	-	350,000
Balance at September 30, 2011	<u>19,517,000</u>	<u>\$ 195,000</u>	<u>2,958.3617</u>	<u>\$ -</u>	<u>\$231,617,000</u>	<u>\$ (4,000)</u>	<u>\$(255,275,000)</u>

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Cash Flows  
(unaudited)

	Nine Months ended September 30,	
	2011	2010
Cash flows from operating activities:		
Net loss	\$ (2,813,000)	\$ (9,840,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Gain on change in fair value of derivative - warrants	(3,312,000)	(6,384,000)
Loss on change in fair value of derivative - preferred stock	470,000	10,455,000
Gain on write-off and negotiated accounts payable	(1,282,000)	(509,000)
Depreciation and amortization	176,000	179,000
Stock option compensation expense	767,000	838,000
Stock and warrants issued for services	700,000	556,000
Change in operating assets and liabilities:		
Receivables	899,000	(4,000)
Inventory	(192,000)	-
Prepaid expenses and other current assets	43,000	13,000
Other assets	(20,000)	12,000
Accounts payable and accrued expenses	(73,000)	(202,000)
Dividends payable	197,000	119,000
Accrued interest payable	(96,000)	(117,000)
Deferred revenue	(1,109,000)	(260,000)
Net cash used in operating activities	(5,645,000)	(5,144,000)
Cash flows from investing activities:		
Capital expenditures	(40,000)	(7,000)
Net cash used in investing activities	(40,000)	(7,000)
Cash flows from financing activities:		
Proceeds from exercise of stock options	-	192,000
Proceeds from common stock issuances, net of costs	-	5,848,000
Net cash provided by financing activities	-	6,040,000
Net increase (decrease) in cash and cash equivalents	(5,685,000)	889,000
Cash and cash equivalents at beginning of period	7,033,000	607,000
Cash and cash equivalents at end of period	\$ 1,348,000	\$ 1,496,000
<i>Supplemental cash flow information:</i>		
Cash paid for interest	\$ 660,000	\$ 440,000
<i>Supplemental disclosure of noncash transactions:</i>		
Shares issued for dividends on preferred stock	1,000	282,000
Preferred stock dividends in dividends payable	\$ 1,327,000	\$ 1,340,000

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

## Access Pharmaceuticals, Inc. and Subsidiaries

### Notes to Condensed Consolidated Financial Statements Nine Months Ended September 30, 2011 and 2010 (unaudited)

#### (1) Interim Financial Statements

The condensed consolidated balance sheet as of September 30, 2011, the condensed consolidated statements of operations for the three and nine months ended September 30, 2011 and 2010, the condensed consolidated statements of stockholders deficit for the three and nine months ended September 30, 2011, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2011 and 2010, were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these interim financial statements be read in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2010. The results of operations for the period ended September 30, 2011 are not necessarily indicative of the operating results which may be expected for a full year. The condensed consolidated balance sheet as of December 31, 2010 contains financial information taken from the audited Access financial statements as of that date.

The report of our independent registered public accounting firm for the fiscal year ended December 31, 2010, 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, as discussed herein and in this Form 10-Q. On November 10, 2011, we closed the sale of approximately 3.71 million shares of our common stock and warrants to purchase 3.71 million shares of our common stock for gross proceeds of approximately \$5.39 million. 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 2012. If we are unable to obtain adequate capital funding in the future or enter into future license agreements for our products, 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.

#### (2) Intangible Assets

Intangible assets consist of the following (in thousands):

	September 30, 2011		December 31, 2010	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated Amortization
Amortizable intangible assets				
Patents	\$ 2,624	\$ 2,209	\$ 2,624	\$ 2,050

Amortization expense related to intangible assets totaled \$53,000 and \$159,000 for each of the three and nine months ended September 30, 2011 and totaled \$53,000 and \$159,000 for each of the three and nine months ended September 30, 2010. The aggregate estimated amortization expense for intangible assets remaining as of September 30, 2011 is as follows (in thousands):

2011	\$	53
2012		82
2013		44
2014		44
2015		44
over 5 years		<u>148</u>
Total	\$	<u>415</u>

### (3) Notes Payable

As of September 30, 2011, we had one convertible note outstanding in the principal amount of \$5.5 million. One half of the note (\$2.75 million) is due November 17, 2011, five days after the closing of our equity financing and the remaining \$2.75 million under the note is due on September 13, 2012.

### (4) Liquidity

The Company generated net loss allocable to common stockholders of \$4,140,000 for the nine months ended September 30, 2011 and a loss of \$9,328,000 for the year ended December 31, 2010. At September 30, 2011, our working capital deficit was \$12,581,000. As of September 30, 2011, we had one convertible note outstanding in the principal amount of \$5.5 million. One half of the note (\$2.75 million) is due November 16, 2011, five days after the closing of our equity financing and the remaining \$2.75 million under the note is due on September 13, 2012. Management believes that our current cash, revenues from MuGard sales and expected license fees should fund our expected burn rate into the third quarter of 2012. On November 10, 2011, we closed the sale of approximately 3.71 million shares of our common stock and warrants to purchase 3.71 million shares of our common stock for gross proceeds of approximately \$5.39 million. We will require additional funds to continue operations. These funds are expected to come from the future sales of equity and/or license agreements. If we are unable to obtain adequate capital funding in the future or enter into future license agreements for our products, 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.

### (5) Fair Value of Financial Instruments

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

Effective January 1, 2008, we adopted fair value measurement guidance issued by the FASB related to financial assets and liabilities which define 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.
- 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 September 30, 2011 and December 31, 2010 are summarized below:

<u>(in thousands)</u>					
Description	As of September 30, 2011	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability- warrants	\$ 1,775	\$ -	\$ 1,775	\$ -	\$ 3,312
preferred stock	\$ 6,310	\$ -	\$ -	\$ 6,310	\$ (470)

<u>(in thousands)</u>					
Description	As of December 31, 2010	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability- warrants	\$ 5,087	\$ -	\$ 5,087	\$ -	\$ 4,621
preferred stock	\$ 5,840	\$ -	\$ -	\$ 5,840	\$ (5,840)

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 September 30, 2011 and December 31, 2010, 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.

#### **(6) Stock Based Compensation**

For the three and nine months ended September 30, 2011, we recognized stock-based compensation expense of \$344,000 and \$767,000. For the three and nine months ended September 30, 2010 we recognized stock-based compensation expense of \$284,000 and \$838,000.

The following table summarizes stock-based compensation for the three months ended September 30, 2011 and 2010:

	Three months ended September 30,		Nine months ended September 30,	
	2011	2010	2011	2010
Research and development	\$ 124,000	\$ 210,000	\$ 336,000	\$ 575,000
General and administrative	220,000	74,000	431,000	263,000
Stock-based compensation expense included in operating expense	\$ 344,000	\$ 284,000	\$ 767,000	\$ 838,000

For the three and nine months ended September 30, 2011 we granted 0 and 575,000 stock options, respectively. For the three and nine months ended September 30, 2010 we granted 0 and 640,000 stock options, respectively.

Our weighted average Black-Scholes fair value assumptions used to value the 2011 and 2010 first nine months grants are as follows:



	<u>9/30/11</u>		<u>9/30/10</u>	
Expected life <sup>(b)</sup>	6.04 yrs		5.7 yrs	
Risk free interest rate	2.0	%	2.3	%
Expected volatility <sup>(a)</sup>	119	%	123	%
Expected dividend yield	0.0	%	0.0	%

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(a) Reflects movements in our stock price over the most recent historical period equivalent to the expected life.

(b) Based on the simplified method.

### **(7) Subsequent Events (Unaudited)**

On November 10, 2011, we closed the sale of approximately 3.71 million shares of our common stock and warrants to purchase 3.71 million shares of our common stock for gross proceeds of approximately \$5.39 million. We sold the shares and warrants for \$1.45 per unit (each consisting of one share of common stock and a warrant to purchase 0.5 of a share of common stock at \$1.67 per whole share exercisable for two and one half years and a warrant to purchase 0.5 of a share of common stock at \$2.00 per whole share exercisable for five years).



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No dealer, salesperson or other person has been authorized to give any information or to make any representations other than those contained in this Prospectus in connection with the offering made by this Prospectus, and, if given or made, such information or representations must not be relied upon as having been authorized by the Company or the selling stockholders. This Prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities other than those specifically offered hereby or an offer to sell or a solicitation of an offer to buy any of these securities in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation. Except where otherwise indicated, this Prospectus speaks as of the effective date of the Registration Statement. Neither the delivery of this Prospectus nor any sale hereunder shall under any circumstances create any implication that there has been no change in the affairs of the Company since the date hereof.

ACCESS PHARMACEUTICALS, INC.

8,615,517

**SHARES OF COMMON STOCK**

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**PROSPECTUS**

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**JANUARY 20, 2012**