

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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PRE-EFFECTIVE AMENDMENT NO. 3 TO  
FORM S-1  
REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

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**ACCESS PHARMACEUTICALS, INC.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**3841**  
(Primary Standard Industrial  
Classification Code Number)

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

**2600 Stemmons Freeway, Suite 176  
Dallas, Texas 75207  
(214) 905-5100**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive  
Offices)

**Stephen B. Thompson  
Chief Financial Officer  
Access Pharmaceuticals, Inc.  
2600 Stemmons Freeway, Suite 176  
Dallas, Texas 75207  
(214) 905-5100**

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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**Approximate date of commencement of proposed sale to public: As soon as practicable after the effective date hereof.**

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration number of the earlier effective registration statement for the same offering.

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

Larger accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

#### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price	Amount of registration fee(1)
Common Stock, par value \$0.01 per share	\$ —	\$ —
Warrants to purchase Common Stock	\$ —	— (3)
Common Stock issuable upon exercise of the Warrants (2)	\$ —	— (3)
Underwriter’s Warrants to purchase Common Stock	—	— (3)
Common Stock issuable upon exercise of Underwriter’s Warrants(2)	—	— (3)
Total	\$ 7,000,000	\$ 802.20 (4)

(1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered. Includes shares and warrants that may be purchased by the underwriters to cover over-allotments, if any.

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional shares of common stock as may be issuable upon exercise of warrants registered hereunder as a result of stock splits, stock dividends, or similar transactions.

(3) No fee required pursuant to Rule 457(g).

(4) The registrant previously paid a registration fee of \$1,146.00.

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(A) OF THE**

**SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SECTION 8(A), MAY DETERMINE.**

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**INFORMATION CONTAINED HEREIN IS SUBJECT TO COMPLETION OR AMENDMENT. A REGISTRATION STATEMENT RELATING TO THESE SECURITIES HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION. THESE SECURITIES MAY NOT BE SOLD UNTIL THE REGISTRATION STATEMENT BECOMES EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT A SOLICITATION OF AN OFFER TO BUY THESE SECURITIES IN ANY STATE IN WHICH AN OFFER, SOLICITATION, OR SALE IS NOT PERMITTED.**

**SUBJECT TO COMPLETION, DATED JUNE 25, 2012**

Preliminary Prospectus

## **ACCESS PHARMACEUTICALS, INC.**

\_\_\_\_\_ SHARES OF COMMON STOCK  
WARRANTS TO PURCHASE UP TO \_\_\_\_ SHARES OF COMMON STOCK

We are offering \_\_\_ shares of our common stock and warrants to purchase up to \_\_\_ shares of our common stock in this offering (and the shares of common stock issuable from time to time upon exercise of the offered warrants). Each share of common stock is being sold together with a \_\_\_\_-year warrant to purchase \_\_\_\_ share of common stock at an exercise price of \$\_\_\_ per share. The shares of common stock and warrants will be issued separately.

Our common stock is presently quoted on the Over-the-counter Bulletin Board (the “OTC BB”) under the symbol “ACCP”. On June 22, 2012, the last reported sale price of our common stock on the OTC BB was \$0.67 per share. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other nationally recognized trading system.

**INVESTING IN THE OFFERED SECURITIES INVOLVES RISKS, INCLUDING THOSE SET FORTH IN THE “RISK FACTORS” SECTION OF THIS PROSPECTUS BEGINNING ON PAGE 6.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

	Per Share	Per Warrant	Total
Public offering price	\$	\$	\$
Underwriting discount <sup>1</sup>	\$	\$	\$
Proceeds before expenses, to us	\$	\$	\$

<sup>1</sup> See “Underwriting” on page 67 for a description of the compensation payable to the underwriters.

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The underwriters may also purchase up to an additional \_\_\_\_\_ shares and/or additional warrants to purchase up to \_\_\_\_\_ shares of common stock from us at the public offering price for each security, less the underwriting discount, within 30 days from the date of this prospectus to cover over-allotments, if any. If the underwriters exercise the option in full, the total public offering price will be \$\_\_\_\_\_, the total underwriting discount will be \$\_\_\_\_\_ and the total proceeds, before expenses, to us will be \$\_\_\_\_\_.

The underwriters expect to deliver the shares and warrants against payment on or about \_\_\_\_\_, 2012, subject to customary closing conditions.

## **Cowen and Company**

THE DATE OF THIS PROSPECTUS IS \_\_\_\_\_, 2012.

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**You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that which is contained in this prospectus. This prospectus may be used only where it is legal to sell these securities. The information in this prospectus may only be accurate on the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of securities.**

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## PROSPECTUS SUMMARY

### 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 this prospectus together with additional information described below under the heading "Where You Can Find More Information". As used in this Prospectus the term “product” refers to both “products” and “product candidates”.

### 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 and medical device products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one marketed product, two products at Phase 2 of clinical development and several products in pre-clinical development. The success of our 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.

#### Marketed Product

- MuGard™ is our marketed product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the FDA. We launched MuGard in the United States in the fourth quarter of 2010. We are continuing the training of our third-party MuGard representatives on the product, on the oral mucositis condition and on our sales strategy. MuGard prescriptions are growing quarterly and we have placed emphasis on our sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake. MuGard has been launched in Germany, Italy, the UK, Greece and the Nordic countries by SpePharm, formerly our commercial partner in the E.U. By mutual agreement, the partner agreement with SpePharm has been terminated. Per terms of the agreement, MuGard will continue to be commercially available for up to six months in Europe through SpePharm. We are actively seeking a new European commercial partner for MuGard. Our China partners have received an acceptance letter from the State Food and Drug Administration of the People’s Republic of China which provides marketing approval in China.

#### Product Candidates

- 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. A second combination study was initiated in the fourth quarter of 2011 combining ProLindac with gemcitabine for the treatment of cholangiocarcinoma. Clinical studies of other indications including liver, colorectal and ovarian cancer are under consideration by Jiangsu Aosaikang Pharmaceutical Co., Ltd, our licensee for ProLindac in China. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has had annual sales in excess of \$2.0 billion.
- 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 a number of peptides and RNAi therapeutics. We have signed agreements with several companies regarding the sponsored development of CobOral drug

delivery formulations of proprietary and non-proprietary actives.



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

## 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 Regulatory Approval China
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
CodaCyte®-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 Developments

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

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

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

other than liquidated damages that may have already accrued relating to such inability to register such shares.

### **Other Key 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.

In various news releases 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, and 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 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 promissory note. The agreement provided for an extension of 50% of the note (\$2.75 million) until September 13, 2012, and requires the payment of \$2.75 million upon the closing of an equity financing by the Company which payment was made in November 2011, as described above. The amendment provided the note holder with a security interest in certain of our assets and required an interest payment on August 15, 2011, which was paid.

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.

## **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

Common stock offered by us: \_\_\_\_\_ shares

Common stock to be outstanding after this offering: \_\_\_\_\_ shares

Warrants we are offering: We are offering warrants to purchase up to \_\_\_\_\_ shares of common stock that will be exercisable during the period commencing on the date of original issuance and ending \_\_\_ years from such date at an exercise price of \$\_\_\_\_ per share of common stock, subject to adjustment. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the warrants. There is no established public trading market for the warrants, and we do not expect a market to develop. In addition, we do not intend to apply for listing of the warrants on any national securities exchange or other nationally recognized trading system.

Over-allotment option: We have granted to the underwriters an option to purchase up to \_\_\_ additional shares of common stock and/or additional warrants to purchase up to \_\_\_ shares at the public offering prices set forth on the cover page of this prospectus, less the underwriting discount, to cover over-allotments, if any. This option is exercisable for a period of 30 days.

Use of proceeds: We expect to use the proceeds received from the offering to further develop our products and product candidates and for general working capital purposes, including the payment of outstanding debt.

Trading market: Our common stock is quoted on the OTC Bulletin Board under the symbol "ACCP".

Risk Factors: See "Risk Factors" beginning on page 6 and the other information in this prospectus for a discussion of some of the factors you should consider before you decide to invest in our securities.

The total number of shares of our common stock outstanding is 24,163,918 and excludes the following:

- 1,053,346 shares of common stock reserved for future issuance under our equity incentive plans. As of June 25, 2012, there were options to purchase 2,816,284 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$2.19 per share;
- 15,783,943 shares of common stock issuable upon exercise of outstanding warrants as of June 25, 2012 with exercise prices ranging from \$1.32 per share to \$6.00 per share; and
- \_\_\_\_\_ shares of common stock that will be issued upon exercise of warrants at an exercise price of \$\_\_\_ per share sold in this offering.
- 20,264,551 shares of our common stock initially issuable upon conversion of Series A Cumulative Convertible Preferred Stock, subject to adjustment; and
- additional shares of common stock which may be issuable if the conversion price of our preferred stock is lowered as a result of this offering

Except as otherwise indicated, all information in this prospectus assumes no exercise by the representative of its over-allotment option.

## SUMMARY CONDENSED CONSOLIDATED FINANCIAL INFORMATION

The following summary selected condensed consolidated financial information as of and for the years ended December 31, 2011 and 2010, have been derived from our audited financial statements. The financial information as of and for the three months ended March 31, 2012 and 2011 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.

<b>(in thousands, except per share amounts)</b>	<u>For the Three Months</u> <u>Ended March 31,</u>		<u>For the Year</u> <u>Ended</u> <u>December 31,</u>	
	2012	2011	2012	2010
	(unaudited)	(unaudited)		
<b>Consolidated Statement of Operations:</b>				
Total revenues	\$ 1,855	\$ 150	\$ 1,848	\$ 481
Loss from operations	(689)	(2,149)	(7,876)	(7,757)
Interest and miscellaneous income	1	5	1,334	2,046
Interest and other expense	(169)	(167)	(963)	(607)
Warrant extension expense	(2,316)	-	-	-
Gain on change in fair value of derivative warrants	741	1,235	3,580	4,621
Gain (loss) on change in fair value of derivative preferred stock	(2,460)	(823)	1,410	(5,840)
Net loss before state income taxes	(4,892)	(1,899)	(2,515)	(7,537)
State income taxes	-	-	(17)	-
Net loss	(4,892)	(1,899)	(2,532)	(7,537)
Preferred stock dividends	(440)	(438)	(1,774)	(1,791)
Net loss allocable to common stockholders	\$(5,332)	\$ (2,337)	\$(4,306)	\$(9,328)
<b>Common Stock Data:</b>				
Basic and diluted net loss per common share				
Net loss allocable to common stockholders	\$ (0.22)	\$ (0.12)	\$ (0.22)	\$ (0.60)
Weighted average basic and diluted common shares outstanding	24,145	19,242	19,983	15,633

	<u>March 31,</u>		<u>December 31,</u>	
	2012	2011	2011	2010
	(unaudited)	(unaudited)		
<b>Consolidated Balance Sheet Data:</b>				
Cash and cash equivalents	\$ 1,365	\$6,174	\$2,460	\$ 7,033
Total assets	3,196	6,876	3,785	8,771
Deferred revenue	3,037	4,643	3,549	4,729
Derivative liability warrants	766	3,852	1,507	5,087
Derivative liability preferred stock	6,890	6,663	4,430	5,840
Debt	2,750	5,500	2,750	5,500
Total liabilities	23,359	29,580	21,391	29,566
Total stockholders' deficit	(20,163)	(22,704)	(17,606)	(20,795)

## 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, 2011, 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 \$255.4 million through December 31, 2011. Net losses allocable to common stockholders for the years ended 2011 and 2010 were \$4.3 million and \$9.3 million, respectively. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop clinical drug candidates and from the associated administrative costs. We expect to incur additional operating losses over the next several years. We also expect cumulative losses to increase if we expand research and development efforts and preclinical and clinical trials. Our net cash burn rate for the year ended December 31, 2011 was approximately \$602,000 per month. We project our cash disbursements from operations for the next twelve months to be approximately \$550,000 per month, excluding offsetting product and royalty revenues as well as the potential repayment of our note payable due September 13, 2012. 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 platinate has taken longer to progress through clinical trials than originally planned. The failure to adequately demonstrate the safety and efficacy of a drug candidate under development could delay or prevent regulatory approval of the drug candidate. A delay or failure to receive regulatory approval for any of our drug candidates could prevent us from successfully commercializing such candidates and we could incur substantial additional expenses in our attempt to further develop such candidates and obtain future regulatory approval.

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

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

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

Our research and development processes involve the controlled use of hazardous materials. We are subject to a variety of federal, state and local governmental laws and regulations related to the use, manufacture, storage, handling and disposal of such material and certain waste products. In the event of an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

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

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

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

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



**We depend on licenses from third parties and the maintenance of our licenses 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 will be required to pay liquidated damages to certain investors if we do not maintain an effective registration statement relating to common stock issuable upon conversion of 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 will 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 June 25, 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. Based on our evaluation, our management concluded that there is a material weakness in our internal control over financial reporting. The material weakness identified did not result in the restatement of any previously reported financial statements or any related financial disclosure, nor does management believe that it had any effect on the accuracy of the Company's financial statements for the current reporting period. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness relates to the monitoring and review of work performed by our Chief Financial Officer in the preparation of audit and financial statements, footnotes and financial data provided to the Company's registered public accounting firm in connection with the annual audit. All of our financial reporting is carried out by our Chief Financial Officer. This lack of accounting staff results in a lack of segregation of duties and accounting technical expertise necessary for an effective system of internal control. In order to mitigate this material weakness to the fullest extent possible, all financial reports are reviewed by the Chief Executive Officer as well as the Chairman of the Audit Committee for reasonableness. All unexpected results are investigated. At any time, if it appears that any control can be implemented to continue to mitigate such weaknesses, it is immediately implemented. As soon as our finances allow, we will hire sufficient accounting staff and implement appropriate procedures for monitoring and review of work performed by our Chief Financial Officer. Because of the material weakness described above, management concluded that, as of December 31, 2011, our internal control over financial reporting was not effective based on the criteria established in Internal Control-Integrated Framework issued by COSO.

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

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

**Risks relating to this Offering**

**We will have broad discretion over the use of the net proceeds from this offering.**



We intend to use the net proceeds of this offering to further develop our products and product candidates and for working capital and general corporate purposes, including the payment of outstanding debt. Our judgment may not result in positive returns on your investment and you will not have an opportunity to evaluate the economic, financial, or other information upon which we base our decisions.

**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 24,163,918 shares of common stock outstanding as of June 25, 2012, 19,866,473 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 15,783,943 shares issuable upon exercise of outstanding warrants could also lower the market price of our common stock.

**You will experience immediate and substantial dilution as a result of this offering and may experience additional dilution in the future.**

Since the public offering price of the securities offered pursuant to this prospectus is higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. See “Dilution” in this prospectus for a more detailed discussion of the dilution you will incur if you purchase securities in this offering.

In addition, in the past, we issued options and warrants to acquire shares of common stock. To the extent these options are ultimately exercised, you will sustain future dilution. We may also acquire or license other technologies or finance strategic alliances by issuing equity, which may result in additional dilution to our stockholders.

**There is no public market for the warrants to purchase common stock in this offering.**

There is no established public trading market for the warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply for listing the warrants on any securities exchange. Without an active market, the liquidity of the warrants will be limited.

If a registration statement covering the shares issuable upon exercise of the warrants offered hereby is no longer effective, the warrants will be issued with restrictive legends unless such shares are eligible for sale under Rule 144.

**We will need additional capital in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.**

Based on our proposed use of proceeds, we will likely need significant additional financing, which we may seek to raise through, among other things, public and private equity offerings and debt financing. Any equity financing will be dilutive to existing stockholders, and any debt financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms, or at all.

**Risks related to our common stock**

**We have a secured promissory note outstanding in the principal 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 principal 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 our 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. Under the terms of this offering, we anticipate selling shares of our common stock for \$\_\_\_\_\_ per share together with a \_\_\_\_\_-year warrant to purchase \_\_\_\_\_ share of common stock at an exercise price of \$\_\_\_\_ per share. This will result in the conversion price of outstanding Series A Cumulative Convertible Preferred Stock automatically decreasing to \$\_\_\_\_\_ per share. This lower conversion price will entitle our holders of Series A Cumulative Convertible Preferred to acquire a greater number of shares of our common stock than they otherwise would have been able to obtain if not for the anti-dilution price adjustment.

**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 together with a \_\_\_\_\_-year warrant to purchase \_\_\_\_\_ share of common stock at an exercise price of \$\_\_\_\_ per share. Under the terms of this offering, we anticipate selling shares of our common stock for \$\_\_\_\_\_ per share. This will result in the exercise price of certain previously issued warrants automatically decreasing to \$\_\_\_\_\_ 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 47.9%, 9.4%, 6.0% and 5.0%, respectively, of our common stock on an as converted basis as of June 25, 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.

## 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.

## USE OF PROCEEDS

The net proceeds of this offering after deducting the underwriters' discount and the estimated offering expenses payable by us will be approximately \$\_\_\_\_\_, assuming no exercise of the warrants offered hereby. We will use the net proceeds from this offering to further develop our products and product candidates and for working capital and other general corporate purposes, including the payment of outstanding debt. Pending any use, we plan to invest the net proceeds in investment grade, short-term, interest-bearing securities.

If a warrant holder elects to pay the exercise price, rather than exercising the warrants on a "cashless" basis, we may also receive proceeds from the exercise of warrants. We cannot predict when or if the warrants will be exercised. It is possible that the warrants may expire and may never be exercised.

## DILUTION

Purchasers of the securities offered by this prospectus will suffer immediate and substantial dilution in the net tangible book value per share of the common stock they purchase. Our net tangible book value as of December 31, 2011 was approximately \$ \_\_\_\_\_ per share of our common stock. Net tangible book value per share represents the amount of total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding as of December 31, 2011.

Dilution in net tangible book value per share represents the difference between the amount per share paid by purchasers in this offering and the net tangible book value per share of our common stock immediately after this offering. After giving effect to the sale of \_\_\_\_\_ shares of common stock and warrants to purchase up to \_\_\_\_\_ shares of our common stock in this offering at the combined public offering price of \$ \_\_\_\_\_ per share and warrant, and after deducting the underwriting discount and the estimated offering expenses payable by us, our as adjusted net tangible book value as of December 31, 2011 would have been approximately \$ \_\_\_\_\_ per share of common stock. This represents an immediate increase in net tangible book value of \$ \_\_\_\_\_ share of common stock to our existing stockholders and an immediate dilution in net tangible book value of \$ \_\_\_\_\_ per share of common stock to purchasers in this offering, attributing none of the combined public offering price to the warrants offered hereby. The following table illustrates this per share dilution:

Combined public offering price per share and warrant	\$
Net tangible book value per share as of December 31, 2011	\$
Increase per share attributable to this offering	\$
As adjusted net tangible book value per share as of December 31, 2011 after this offering	\$
Dilution per share to new investors participating in this offering	\$

The above discussion and tables do not include the following:

- 1,053,346 shares of common stock reserved for future issuance under our equity incentive plans. As of June \_\_, 2012, there were 2,776,784 options outstanding under our equity incentive plans with a weighted average exercise price of \$2.19 per share;
- 15,783,943 shares of common stock issuable upon exercise of outstanding warrants as of June \_\_, 2012, with exercise prices ranging from \$1.32 per share to \$6.00 per share;
- \_\_\_\_\_ shares of common stock that will be issued upon exercise of warrants in this offering; and
- additional shares of common stock which may be issuable if the conversion price of our preferred stock is lowered as a result of this offering.

The above discussion and tables assume that our 2,938,3617 shares of Series A Cumulative Convertible Preferred Stock are converted into 20,264,551 shares of common stock at a conversion price of \$1.45 per share.

To the extent that any options or warrants are exercised, new options are issued under our equity incentive plan, or we otherwise issue additional shares of common stock in the future, at a price less than the public offering price, there will be further dilution to new investors.

## PRICE RANGE OF OUR COMMON STOCK

### 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 2012 year-to-date and fiscal years 2011 and 2010. The OTCBB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

		Common Stock	
		<u>High</u>	<u>Low</u>
<b><u>Fiscal Year 2012 Year-to-date</u></b>			
First quarter	\$	1.44	\$ 0.98
Second quarter (through June 22, 2012)		1.23	0.45
<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 June 25, 2012 was approximately 7,000. On June 22, 2012, the closing price for the common stock as quoted on the OTCBB was \$0.67. There were 24,163,918 shares of common stock outstanding at June 25, 2012.

There were 2,938.3617 shares of Series A Cumulative Convertible Preferred Stock convertible into 20,264,551 shares of Common Stock at June 25, 2012.

## Options and Warrants

There are 15,783,943 outstanding warrants and 2,816,284 outstanding options to purchase our common equity as of June 25, 2012.

## Equity Compensation Plan Information

The following table sets forth information as of December 31, 2011 about shares of common stock outstanding and available for issuance under our existing equity compensation plans.

<b>Plan Category</b>	<b>Number of securities to be issued upon exercise of outstanding options warrants and rights</b>	<b>Weighted-average exercise price of outstanding options warrants and rights</b>	<b>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column)</b>
	<b>(a)</b>	<b>(b)</b>	<b>(c)</b>
Equity compensation plans approved by security holders:			
2005 Equity Incentive Plan	2,266,784	\$ 2.17	1,787,929
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>2,324,284</b>	<b>\$ 2.53</b>	<b>2,237,929</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, 2011.

## **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 our 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. The terms of our outstanding preferred stock restrict our ability to pay dividends on our common stock.



## 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 and medical device products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one marketed product, two products at Phase 2 of clinical development and several products in pre-clinical development. The success of our 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.

### Marketed Product

- MuGard™ is our marketed product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the FDA. We launched MuGard in the United States in the fourth quarter of 2010. We are continuing the training of our third-party MuGard representatives on the product, on the oral mucositis condition and on our sales strategy. MuGard prescriptions are growing quarterly and we have placed emphasis on our sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake. MuGard has been launched in Germany, Italy, the UK, Greece and the Nordic countries by SpePharm, formerly our commercial partner in the E.U. By mutual agreement, the partner agreement with SpePharm has been terminated. Per terms of the agreement, MuGard will continue to be commercially available for up to six months in Europe through SpePharm. We are actively seeking a new European commercial partner for MuGard. Our China partners have received an acceptance letter from the State Food and Drug Administration of the People's Republic of China which provides marketing approval in China.

### Product Candidates

- 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. A second combination study was initiated in the fourth quarter of 2011 combining ProLindac with gemcitabine for the treatment of cholangiocarcinoma. Clinical studies of other indications including liver, colorectal and ovarian cancer are under consideration by Jiangsu Aosaikang Pharmaceutical Co., Ltd, our licensee for ProLindac in China. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has had annual sales in excess of \$2.0 billion.
- 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 a number of peptides and RNAi therapeutics. We have signed agreements with several companies regarding the sponsored development of CobOral drug delivery formulations of proprietary and non-proprietary actives.

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

## 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 Regulatory Approval China
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
CodaCyte®-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 Developments

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

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

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

### **Other Key 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.

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, and 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 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 promissory note. The agreement provided for an extension of 50% of the note (\$2.75 million) until September 13, 2012, and requires the payment of \$2.75 million upon the closing of an equity financing by the Company which payment was made in November 2011, as described above. The amendment provided the note holder with a security interest in certain of our assets and required an interest payment on August 15, 2011, which was paid.

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 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 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 plan is to 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 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 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 Three Months Ended March 31, 2012 with the Three Months Ended March 31, 2011**

Our licensing revenue for the first quarter of 2012 was \$1,262,000 as compared to \$87,000 for the same period of 2011, an increase of \$1,175,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. In the first quarter of 2012, we finalized the negotiations for the termination of the license from our European partner for MuGard and recognized all of the previously received license fees (\$706,000) that were recorded in deferred revenue and a \$500,000 termination fee.

Product sales of MuGard in the United States totaled \$572,000 for the first quarter of 2012 as compared with \$13,000 for the same period of 2011, an increase of \$559,000.

We recorded royalty revenue for MuGard in Europe of \$21,000 for first quarter of 2012 as compared to \$20,000 for the same period of 2011, an increase of \$1,000.

Sponsored research and development revenues were \$30,000 for the first quarter of 2011 as compared to none for the same period of 2012, a decrease of \$30,000. The revenues in 2011 were the result of various collaborations on our CobOral and CobaCyte projects.

Total research and development spending for the first quarter of 2012 was \$974,000, as compared to \$1,120,000 for the same period of 2011, a decrease of \$146,000. The decrease in expenses was primarily due to:

- decreased clinical development with trials for ProLindac, MuGard and Thiarabine (\$176,000);
- decreased scientific consulting costs (\$101,000);
- decreased external lab costs for studies (\$60,000);
- other net decreases in research spending (\$30,000); and
- increased salary and related costs (\$221,000) due to additional staff and stock issuances to employees for bonuses in lieu of cash payments.

Product costs for MuGard in the United States were \$537,000 for the first quarter of 2012 as compared to \$92,000 for the same period in 2011, an increase of \$445,000.

Total general and administrative expenses were \$979,000 for the first quarter of 2012, a decrease of \$47,000 compared to the same period in 2011 of \$1,026,000. The decrease in expenses was due primarily to the following:

- decreased general business consulting expenses due to less use of outside consultants in 2012 (\$240,000) versus the same period in 2011;
- decreased net other general and administrative expenses (\$20,000);
- increased salary and related costs (\$133,000) due to additional staff and stock issuances to employees for bonuses in lieu of cash payments; and
- increased directors fees due to stock issuances in lieu of cash payments to directors (\$80,000).

Depreciation and amortization was \$54,000 for the first quarter of 2012 as compared to \$61,000 for the same period in 2011, a decrease of \$7,000.

Total operating expenses for the first quarter of 2012 year were \$2,544,000 as compared to total operating expenses of \$2,299,000 for the same period of 2011, an increase of \$245,000 for the reasons listed above.

Interest and miscellaneous income was \$1,000 for the first quarter of 2012 as compared to \$5,000 for the same period of 2011, a decrease of \$4,000.

Interest and other expense was \$169,000 for the first quarter of 2012 as compared to \$167,000 in the same period of 2011, an increase of \$2,000.

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

We recorded a gain related to warrants classified as derivative liabilities of \$741,000 for the first quarter of 2012 as compared to \$1,235,000 for the same period of 2011. We recorded a derivative for warrants in 2009 when the fair value of the warrants that were issued with our Series A Convertible Preferred Stock were reclassified from equity per the requirements of accounting guidance as a result of the repricing feature.

We recorded a loss for the derivative liability related to preferred stock of \$2,460,000 for the first quarter of 2012 and a loss of \$823,000 for the same period of 2011. We recorded a derivative in 2010 per the requirements of accounting guidance due to the possibility of repricing our Series A Convertible Preferred Stock if we sold our common stock at a price below the original conversion price.

Preferred stock dividends of \$440,000 were accrued for the first quarter of 2012 and \$438,000 for the same period of 2011, an increase of \$2,000. Dividends are due semi-annually in either cash or common stock.

Net loss allocable to common stockholders for the first quarter of 2012 was \$5,332,000, or a \$0.22 basic and diluted loss per common share, compared with a net loss of \$2,337,000, or a \$0.12 basic and diluted loss per common share, for the same period in 2011, an increased loss of \$2,995,000.

### **Comparison of Years Ended December 31, 2011 and 2010**

Our licensing revenue for the year ended December 31, 2011 was \$1,181,000 as compared to \$347,000 for the same period of 2010, an increase of \$834,000. 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.

Product sales of MuGard in the United States totaled \$548,000 for the year ended December 31, 2011 as compared with \$8,000 for the same period of 2010, an increase of \$540,000. Our first sales were recorded in the fourth quarter of 2010.

We recorded royalty revenue for MuGard in Europe of \$89,000 for the year ended December 31, 2011 as compared to \$76,000 for the same period of 2010, an increase of \$13,000.

Sponsored research and development revenues were \$30,000 for the year ended December 31, 2011 as compared to \$50,000 for the same period of 2010, a decrease of \$20,000. The revenues in 2011 and 2010 are for research various collaborations on our CobOral and CobaCyte projects.

Total research and development spending for the year ended December 31, 2011 was \$4,200,000, as compared to \$3,349,000 for the same period of 2010, an increase of \$851,000. The increase in expenses was primarily due to:

- increased clinical development with trials for ProLindac, MuGard and Thiarabine (\$610,000);
- increased salary and related costs due to new employees (\$357,000);
- increased external lab costs for CobOral and CobaCyte (\$152,000)
- other net increases in research spending (\$76,000).
- decreased stock compensation expense for lower expense of option grants for research and development employees (\$194,000); and
- lower external development expenses for ProLindac (\$150,000). The product was made in 2010 and is used in the clinical trials ongoing this year.

Product costs for MuGard in the United States were \$1,216,000 for the year ended December 31, 2011 as compared to \$140,000 for the same period in 2010, an increase of \$1,076,000. MuGard was launched in the fourth quarter of 2010.

Total general and administrative expenses were \$4,075,000 for the year ended December 31, 2011, a decrease of \$436,000 compared to the same period in 2010 of \$4,511,000. 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 (\$967,000) versus the same period in 2011;
- decreased patent and license fees (\$77,000);
- decreased net other general and administrative expenses (\$23,000);





- increased salary and related costs (\$262,000);
- increased stock compensation expense due to higher expense of option grants for general and administrative employees and directors (\$246,000); and
- increased rent expenses (\$123,000) due to additional office space.

Depreciation and amortization was \$233,000 for the year ended December 31, 2011 as compared to \$238,000 for the same period in 2010.

Total operating expenses for the year ended December 31, 2011 were \$9,727,000 as compared to total operating expenses of \$8,238,000 for the same period of 2010, an increase of \$1,489,000 for the reasons listed above.

Interest and miscellaneous income was \$1,334,000 for the year ended December 31, 2011 as compared to \$2,046,000 for the same period of 2010, a decrease of \$712,000. In 2010, we recorded miscellaneous income for one time grants of \$1,479,000 from Qualifying Therapeutic Discovery Project Grants from the United States. Miscellaneous income was \$804,000 in 2011 due to negotiated payables and write-off of other accounts payable and offset by \$37,000 of other miscellaneous income. Interest income is comparable to the same period in 2010.

Interest and other expense was \$963,000 for the year ended December 31, 2011 as compared to \$607,000 in the same period of 2010, an increase of \$356,000. 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 \$3,580,000 for the year ended December 31, 2011 as compared to \$4,621,000 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 gain for the derivative liability related to preferred stock of \$1,410,000 for the year ended December 31, 2011 and a loss of \$5,840,000 for the same period of 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 \$1,774,000 were accrued for the year ended December 31, 2011 and \$1,791,000 for the same period of 2010, a decrease of \$17,000. 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 year ended December 31, 2011 was \$4,306,000, or a \$0.22 basic and diluted loss per common share, compared with net loss of \$9,328,000, or a \$0.60 basic and diluted loss per common share for the same period in 2010, a decreased loss of \$5,022,000.

## **Liquidity and Capital Resources**

We have funded our operations primarily through private sales of common stock, preferred stock, convertible notes and through licensing agreements. Our principal source of liquidity is cash and cash equivalents. Product sales and royalty revenues provided limited funding for operations during the three months ended March 31, 2012. As of March 31, 2012, our cash and cash equivalents were \$1,365,000 and our net cash burn rate for the quarter ended March 31, 2012, was approximately \$365,000 per month. As of March 31, 2012, our working capital deficit was \$10,136,000. Our working capital deficit at March 31, 2012 represented an increase of \$1,259,000 as compared to our working capital deficit as of December 31, 2011 of \$8,877,000. The increase in the working capital deficit at March 31, 2012 reflects three months of net operating costs. As of March 31, 2012, we had one secured promissory note outstanding in the principal amount of \$2.75 million that is due on September 13, 2012.

As of June 25, 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 March 31, 2012 of \$260,773,000. 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 note;
- the ability to establish and maintain collaborative arrangements with corporate partners for the research, development and commercialization of products;
- continued scientific progress in our research and development programs;
- the magnitude, scope and results of preclinical testing and clinical trials;
- the costs involved in filing, prosecuting and enforcing patent claims;
- the costs involved in conducting clinical trials;
- competing technological developments;
- the cost of manufacturing and scale-up;
- the ability to establish and maintain effective commercialization arrangements and activities; and
- successful regulatory filings.

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

(in thousands) Project	Twelve Months ended December 31,		Inception To Date (1)
	2011	2010	
Polymer Platinite (ProLindac™)	\$ 2,239	\$ 2,697	\$ 33,062
Mucoadhesive Liquid Technology (MLT)	1,310	329	3,257
Others (2)	651	323	6,411
Total	\$ 4,200	\$ 3,349	\$ 42,730

- (1) Cumulative spending from inception of the Company or project through December 31, 2011.
- (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 in the past three years.

### **Climate Change**

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

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

The preparation of our consolidated financial statements in conformity with accounting principles generally accepted in the 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, 2011 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, 2011 and for the year then ended, management believes no impairment of our intangible assets exists.

#### *Receivables*

Receivables are reported in the balance sheets at the outstanding amount net of an allowance for doubtful accounts. We continually evaluate the creditworthiness of our customers and their financial condition and generally does not require collateral. The allowance for doubtful accounts is based upon reviews of specific customer balances, historic losses, and general economic conditions. As of December 31, 2011 and 2010, no allowance was recorded as all accounts are considered collectible.

#### *Revenues*

Our revenues are generated from licensing, research and development agreements, royalties and product sales. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104), *Revenue Recognition*. License revenue is recognized over the remaining life of the underlying patent. Research and development revenues are recognized as services are performed. Royalties are recognized in the period of sales. We recognize revenue for MuGuard product sales at the time title transfers to our customers, which occurs at the time product is delivered to our customers.

#### *Product costs*

We recognize all product costs, costs of goods sold, logistics, sales and marketing and samples at the time incurred.

#### *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, 2011 and 2010 was approximately \$1,066,000 and \$1,015,000, respectively.

#### *Recent Accounting Pronouncements*

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. Upon adoption, we will have the option to report total comprehensive income, including components of net income and components of other comprehensive income, as a single continuous statement or in two separate but consecutive statements. We do not anticipate the adoption of this guidance will have a material impact on our financial statements.

#### **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 and medical device products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one marketed product, two products at Phase 2 of clinical development and several products in pre-clinical development. The success of our 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.

### **Marketed Product**

- MuGard™ is our marketed product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the FDA. We launched MuGard in the United States in the fourth quarter of 2010. We are continuing the training of our third-party MuGard representatives on the product, on the oral mucositis condition and on our sales strategy. MuGard prescriptions are growing quarterly and we have placed emphasis on our sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake. MuGard has been launched in Germany, Italy, the UK, Greece and the Nordic countries by SpePharm, formerly our commercial partner in the E.U. By mutual agreement, the partner agreement with SpePharm has been terminated. Per terms of the agreement, MuGard will continue to be commercially available for up to six months in Europe through SpePharm. We are actively seeking a new European commercial partner for MuGard. Our China partners have received an acceptance letter from the State Food and Drug Administration of the Peoples Republic of China which provides marketing approval in China.

### **Product Candidates**

- 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. A second combination study was initiated in the fourth quarter of 2011 combining ProLindac with gemcitabine for the treatment of cholangiocarcinoma. Clinical studies of other indications including liver, colorectal and ovarian cancer are under consideration by Jiangsu Aosaikang Pharmaceutical Co., Ltd, our licensee for ProLindac in China. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has had annual sales in excess of \$2.0 billion.
- 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 a number of peptides and RNAi therapeutics. We have signed agreements with several companies regarding the sponsored development of CobOral drug delivery formulations of proprietary and non-proprietary actives.

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

## 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 <sup>™</sup>	Access	Mucoadhesive liquid	Mucositis	Launched U.S. and EU Regulatory Approval China
ProLindac <sup>™</sup> (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 <sup>®</sup> Delivery System	Access	Cobalamin	Various	Pre-clinical
CodaCyte <sup>®</sup> -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<sup>™</sup>

#### 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 Pharmaceutical Ltd, under which 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 are ongoing. Also, in 2011, Mr. Anthony Mattola joined Access, as Vice President, Managed Care and Market Access, to assist with managed care, and ongoing reimbursement activities.

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

#### Current Status of MuGard

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

Access initiated a new clinical study of the safety and effectiveness of MuGard in the first quarter of 2011. Accrual into this study is ongoing. The study is a controlled, randomized, double-blinded trial of MuGard with a standard treatment for mucositis as a comparator in patients receiving chemoradiation for head and neck cancer. Interim results are expected to be announced in mid-2012.

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 worldwide sales in excess of \$2.0 billion in 2010. As is the case with all chemotherapeutic drugs, the use of such compounds is associated with serious systemic side effects. The drug development goal therefore is to enhance delivery of the active drug to the tumor and minimize the amount of active drug affecting normal organs in the body.

Utilizing a biocompatible water-soluble polymer (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 <sup>TM</sup> 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.

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. The company commenced a second combination trial, examining the combination of ProLindac and gemcitabine in cholangiocarcinoma patients, in the fourth quarter of 2011. This study has a similar design to that of the ProLindac/paclitaxel study, and is also being conducted in Europe.

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. A Phase 2 clinical trial in adult AML, ALL and other indications is underway at MD Anderson examining the safety and efficacy of Thiarabine using two different dose regimens with dose escalation. 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 to the extent they are conducted.

We contract with third party contract research organizations to complete our large clinical trials and for data management of all of our clinical trials. Currently, we are preparing for two Phase 2 ProLindac trials to be completed by our licensees in China. Our licensees are funding these trials. We are also conducting an additional Phase 2 clinical study in France.

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 \$4,200,000 and \$3,349,000 on research and development during the years 2011 and 2010, 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 nanoparticles 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.



### Current Status of CobOral and CobaCyte

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

### **Recent Developments**

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

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

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

### **Other Key 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.

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, and 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 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 promissory note. The agreement provided for an extension of 50% of the note (\$2.75 million) until September 13, 2012, and requires the payment of \$2.75 million upon the closing of an equity financing by the Company which payment was made in November 2011, as described above. The amendments provided the note holder with a security interest in certain of our assets and required an interest payment on August 15, 2011, which was paid.

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 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 plan is to 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 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 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.

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

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

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 several U.S. and worldwide 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 several U.S. and worldwide patent applications.

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., Avaxia Biologics, Inc, BioAlliance Pharma S.A., Camurus AB, 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 platinate:

- Cisplatin, marketed by Bristol-Myers Squibb, the originator of the drug, and several generic manufacturers;
- Carboplatin, marketed by Bristol-Myers Squibb in the US; and 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 platinate:

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

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 June 25, 2012, we had fourteen 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 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.



## 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	55	Chairman of the Board*
Jeffrey B. Davis	49	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.	63	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 or 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. Dr. Cvitkovic resigned as director May 24, 2012. 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 currently serves as President and Chief Executive Officer since 2011 and as a director since 2007 of Galena Biopharma; and adjunct Professor, Biosciences at Creighton University. He brings more than 20 years of experience in the biopharmaceutical industry. Prior to joining Galena, starting in 2011, Dr. Ahn was Principal at Pukana Partners, Ltd. which provides strategic consulting to life science companies; and Associate Professor, Global Management at Atkinson Graduate School of Management, Willamette University. He previously served as Professor and Chair, Science & Technology Management, Victoria University at Wellington, New Zealand. Dr. Ahn was also founder, President, and Chief Executive Officer of Hana Biosciences. Prior to joining Hana, he served as Vice President, Hematology and corporate officer at Genentech, Inc., and held positions of increasing responsibility at Amgen and Bristol-Myers Squibb. Dr. Ahn also serves on public and venture capital-backed board of directors for RXi Pharmaceuticals, Mesynthes and ScribesSTAT. Dr. Ahn is the author of over 50 peer reviewed journal articles and books. Dr. Ahn received a B.A. and M.B.A. from Chaminade University; and M.A. from Victoria University. He was a graduate fellow in Economics at Essex University, and obtained a Ph.D. from the University of South Australia. Dr. Ahn is a Henry Crown Fellow at the Aspen Institute.

*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 quoted 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>(2)</u>	<u>Awards (\$)</u>	<u>Awards (\$)</u>	<u>Compensation</u>	
Jeffrey B. Davis Chief Executive Officer	2011	\$ 290,000	\$ -	\$ -	\$ -	\$ -	\$ 290,000
	2010	240,000	-	-	-	-	240,000
David P. Nowotnik, Ph.D. Senior Vice President Research and Development	2011	\$ 309,000	\$ -	\$ 205,000	\$ 13,000	\$ 527,000	
	2010	287,000	-	178,000	2,000	467,000	
Frank A. Jacobucci Vice President, Sales and Marketing	2011	\$ 265,000	\$ 52,000	\$ 74,000	\$ -	\$ 391,000	
	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
Frank A. 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.
- (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 25,000 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 June 25, 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 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 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>	156,000	*	-	*	156,000	*
Mark J. Alvino <sup>(5)</sup>	86,000	*	-	*	86,000	*
Stephen B. Howell, M.D. <sup>(6)</sup>	164,422	*	-	*	164,422	*
David P. Nowotnik, Ph.D. <sup>(7)</sup>	448,450	1.8%	-	*	448,450	1.0%
Frank A. Jacobucci <sup>(8)</sup>	229,157	*	-	*	229,157	*
SCO Capital Partners LLC, SCO Capital Partners LP, and Beach Capital LLC <sup>(9)</sup>	9,535,092	31.6%	14,642,278	72.3%	24,177,370	47.9%
Ayer Capital Partners Master Fund, LP <sup>(10)</sup>	4,915,580	8.9%	-		4,915,580	5.1%
Larry N. Feinberg <sup>(11)</sup>	1,222,443	4.9%	3,015,931	14.9%	4,238,374	9.4%
Lake End Capital LLC <sup>(12)</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 7 persons) <sup>(13)</sup>	1,120,029	4.5%	-	*	1,120,029	2.5%

\* - 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 June 25, 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 25,000 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 an aggregate of 15,000 shares of our common stock, presently exercisable options for the purchase of 71,000 shares of our common stock pursuant to the 2005 Equity Incentive Plan.
- (6) Dr. Howell is known to beneficially own an aggregate of 24,722 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.

- (7) Dr. Nowotnik is known to beneficially own an aggregate of 20,116 shares of our common stock, presently exercisable options for the purchase of 408,334 shares of our common stock pursuant to the 2005 Equity Incentive Plan and 20,000 shares of our common stock pursuant to the 1995 Stock Option Plan.
- (8) Mr. Jacobucci is known to beneficially own an aggregate of 100,407 shares of our common stock and presently exercisable options for the purchase of 128,750 shares of our common stock pursuant to the 2005 Equity Incentive Plan.
- (9) 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.
- (10) 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%.
- (11) 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.
- (12) 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.
- (13) Does not include shares held by SCO Financial Group LLC and affiliates nor Lake End Capital LLC.

## 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 44.1% of the voting securities of Access. During 2011 and 2010, SCO and affiliates charged \$300,000 each year in investor relations fees.

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

Dr. Esteban Cvitkovic, a 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:

Year	Consulting Fees	Expense Reimbursement	Fair Value of Restricted Stock
2011	\$ 139,000	\$ 14,000	\$ 71,000
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 and none in 2011. Dr. Ahn's 2010 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

## 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. As of June 25, 2012 there were 24,163,918 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

Holders 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 including this offering to the extent not waived.

## **Warrants**

As of June 25, 2012, warrants for the issuance of 15,783,943 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of \$1.84 per share, all of which are exercisable through various dates expiring between August 27, 2012 and November 30, 2016. Outstanding warrants to acquire 4,149,464 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.

The following summary description of the material features of the warrants being offered pursuant to this prospectus is necessarily general:

*Term.* The warrants are exercisable beginning on the date of original issuance and at any time up to the date that is \_\_\_ years after such date.

*Exercise Price.* The exercise price of the warrants is \$ \_\_\_ per share of common stock. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, distributions of assets, reclassifications or similar events affecting our common stock.

*Exercisability.* Holders may exercise the warrants beginning on the date of the original issuance and at any time during the term of the warrant. The warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the warrant to the extent that the holder would own more than 4.99% of the outstanding common stock after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the warrants.

*Cashless Exercise.* If, at the time a holder exercises its warrant, there is no effective registration statement registering, or the prospectus contained therein is not available, for an issuance of the shares underlying the warrant to the holder, then in lieu of making the cash payment otherwise contemplated to be made to the Company upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

*Transferability.* Subject to applicable laws and any restrictions on transfer set forth in the warrant, the warrant may be transferred at the option of the holder upon surrender of the warrant to us together with the appropriate instruments of transfer.

*Registration.* So long as any of the warrants are outstanding, the Company shall use its best efforts to cause such post-effective amendments to the registration statement of which this prospectus forms a part or any subsequent registration statement to become effective in compliance with the Securities Act as shall be necessary to enable the sale of shares underlying the warrants, and cause copies of each prospectus forming a part thereof, as then amended, to be delivered to the holders as the holders may reasonably request and as otherwise required by law.

*Authorized Shares.* During the period the warrants are outstanding, we will reserve from its authorized and unissued common stock a sufficient number of shares to provide for the issuance of shares of common stock underlying the warrants upon the exercise of the warrants.

*Exchange Listing.* We do not plan on making an application to list the warrants on the OTC BB, any national securities exchange or other nationally recognized trading system.

*Fundamental Transactions.* In the event of any fundamental transaction, as described in the warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our common stock, then upon any subsequent exercise of a warrant, the holder shall have the right to receive as alternative consideration, for each share of our common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of the Company, if we are the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of our common stock for which the warrant is exercisable immediately prior to such event. Notwithstanding the foregoing, in the event of a change of control as described in the warrants other than one in which a successor entity that is a publicly traded corporation whose stock is quoted or listed for trading on an eligible securities market assumes the warrant such that the warrant shall be exercisable for the publicly traded common stock or equivalent securities of such successor entity, at the request of the holder delivered before the 90<sup>th</sup> day after the consummation of such change of control, the Company (or the successor entity) shall purchase the warrant from the holder by paying to the holder, within five business days after such request (or, if later, on the effective date of the fundamental transaction), cash in an amount equal to the Black Scholes value of the remaining unexercised portion of the warrant on the date of such change of control.

*Right as a Stockholder.* Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holders of the warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their warrants.

*Waivers and Amendments.* Any term of the warrants issued in the offering may be amended or waived with our written consent and the written consent of the holders of warrants representing a majority of the shares of common stock underlying the warrants then outstanding, except that no such action may increase the exercise price of any warrant or decrease the number of shares or class of stock obtainable upon exercise of any warrant without the written consent of the holder 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.

We are a party to a Rights Agreement pursuant to which we agree to provide holders of our common stock with the right to buy shares of preferred stock should a party acquire or beneficially own more than 15% of our common stock without first being exempted by us. Such shares of preferred stock will entitle to the holder to certain voting, dividend and liquidation preferences and is designed to discourage take-over attempts not previously approved by our Board of Directors.

### **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.

## UNDERWRITING

We and the underwriters for the offering named below have entered into an underwriting agreement with respect to the shares of common stock and the warrants offered hereby. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase from us the number of shares of our common stock and warrants set forth opposite its name below. Cowen and Company, LLC is the representative of the underwriters.

**Underwriter**

**Number of Shares**

Cowen and Company, LLC .....

Total.....

\_\_\_\_\_  
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The underwriting agreement provides that the obligations of the underwriters are subject to certain conditions precedent and that the underwriters have agreed, severally and not jointly, to purchase all of the shares and the warrants sold under the underwriting agreement if any of these shares and warrants are purchased, other than those shares and warrants covered by the over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act of 1933, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the shares of common stock and warrants, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

*Over-allotment Option to Purchase Additional Shares.* We have granted to the underwriters an option to purchase up to \_\_ additional shares of common stock and/or additional warrants to purchase up to \_\_ shares at the public offering prices set forth on the cover page of this prospectus, less the underwriting discount. This option is exercisable for a period of 30 days. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the sale of the shares of our common stock and warrants offered hereby. To the extent that the underwriters exercise this option, the underwriters will purchase additional shares and/or warrants from us in approximately the same proportion as shown in the table above.

*Discounts and Commissions.* The following table shows the combined public offering price, the underwriting discount and proceeds, before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option.

We estimate that the total expenses of the offering, excluding underwriting discount, will be approximately \$ \_\_\_\_\_ and are payable by us.

	<b>Total</b>		
	<b>Per Share of Common Stock and per Warrant</b>	<b>Without Over- Allotment</b>	<b>With Over Allotment</b>
Public offering price	\$	\$	\$
Underwriting discount			
Proceeds, before expenses, to us			

We also have agreed to reimburse the underwriters for certain out-of-pocket expenses incurred by them up to \$150,000 in connection with this offering, including reasonable fees and disbursements of counsel to the underwriters. We estimate that the total expenses of the offering payable by us, excluding the underwriting discount, will be approximately \$ \_\_\_\_\_.

We have agreed to issue to the underwriters warrants to purchase 1% of the number of shares of common stock sold in this offering (including any shares of common stock sold in the over-allotment option and excluding any shares of common stock issued upon exercise of any warrants), which issuance is deemed to be underwriting compensation by FINRA. The warrants shall have a five-year term from the effective date of the registration statement of which this prospectus forms a part, an exercise price equal to the exercise price of the warrants sold in this offering, cashless exercise provisions, and the same other terms, conditions, rights and preferences as the warrants sold in this offering, provided, that such warrants will otherwise comply with FINRA Rule 5110(g)(1). As a result, for a period of six months after the issuance date of the warrants, neither the warrants nor any warrant shares issued upon exercise of the warrants shall be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security as permitted by the FINRA.

The underwriters propose to offer the shares of common stock and warrants to the public at the public offering prices set forth on the cover of this prospectus. The underwriters may offer the shares of common stock and the warrants to securities dealers at the public offering prices less a concession not in excess of a combined \$ \_\_\_\_\_ per share of common stock and related warrant. The underwriters may allow, and the dealers may re-allow, a discount not in excess of a combined \$ \_\_\_\_\_ per share of common stock and related warrant to other dealers. If all of the shares and warrants are not sold at the public offering price, the underwriters may change the offering price and other selling terms.

*Discretionary Accounts.* The underwriters do not intend to confirm sales of the shares or warrants to any accounts over which they have discretionary authority.

*Stabilization.* In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions, and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase a security so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the security while the offering is in progress.
- Over-allotment transactions involve sales by the underwriters of securities in excess of the number of securities the underwriters are obligated to purchase. This creates a syndicate short position which may be either a covered short position or a naked short position. In a covered short position, the amount of securities over-allotted by the underwriters is not greater than the amount of securities that they may purchase in the over-allotment option. In a naked short position, the amount of shares involved is greater than the amount of shares in the over-allotment option. The underwriters may close out any short position by exercising their over-allotment option and/or purchasing the securities in the open market.

- Syndicate covering transactions involve purchases of securities in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of securities to close out the short position, the underwriters will consider, among other things, the price of securities available for purchase in the open market as compared with the price at which they may purchase these securities through exercise of the over-allotment option. If the underwriters sell more securities than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying securities in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the securities in the open market that could adversely affect investors who purchase in the offering.

These stabilizing transactions and syndicate covering transactions may have the effect of raising or maintaining the market prices of our common stock and warrants or preventing or retarding a decline in the market prices of our common stock and warrants. As a result, the price of our common stock and warrants in the open market may be higher than they would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock and warrants. These transactions may be effected in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

*Lock-Up Agreements.* Pursuant to certain “lock-up” agreements, we and our executive officers, directors and certain of our other stockholders, have agreed, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of or announce the intention to otherwise dispose of, or enter into any swap, hedge or similar agreement or arrangement that transfers, in whole or in part, the economic consequence of ownership of, directly or indirectly, or make any demand or request or exercise any right with respect to the registration of, or file with the SEC a registration statement under the Securities Act relating to, any common stock or securities convertible into or exchangeable or exercisable for any common stock without the prior written consent of Cowen and Company, LLC, for a period of 90 days after the date of the pricing of the offering. The 90-day restricted period will be automatically extended if (i) during the last 17 days of the 90-day restricted period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the 90-day restricted period, we announce that we will release earnings results or become aware that material news or a material event will occur during the 16-day period beginning on the last day of the 90-day restricted period, in either of which case the restrictions described above will continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event.

*United Kingdom.* Each of the underwriters has represented and agreed that:

- it has not made or will not make an offer of the securities to the public in the United Kingdom within the meaning of section 102B of the Financial Services and Markets Act 2000 (as amended) (FSMA) except to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities or otherwise in circumstances which do not require the publication by us of a prospectus pursuant to the Prospectus Rules of the Financial Services Authority (FSA);
- it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of section 21 of FSMA) to persons who have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 or in circumstances in which section 21 of FSMA does not apply to us; and

- it has complied with and will comply with all applicable provisions of FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

*Switzerland.* The securities will not be offered, directly or indirectly, to the public in Switzerland and this prospectus does not constitute a public offering prospectus as that term is understood pursuant to article 652a or 1156 of the Swiss Federal Code of Obligations.

*European Economic Area.* In relation to each Member State of the European Economic Area (Iceland, Norway and Lichtenstein in addition to the member states of the European Union) that has implemented the Prospectus Directive (each, a Relevant Member State), each underwriter has represented and agreed that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of the securities to the public in that Relevant Member State prior to the publication of a prospectus in relation to the securities that has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that it may, with effect from and including the Relevant Implementation Date, make an offer of the securities to the public in that Relevant Member State at any time:

- to legal entities which are authorized or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;
- to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;
- in any other circumstances which do not require the publication by the issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

Each person in a Relevant Member State who receives any communication in respect of, or who acquires any securities under, the offer contemplated in this prospectus will be deemed to have represented, warranted and agreed to and with us and each underwriter that:

- it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive; and
- in the case of any securities acquired by it as a financial intermediary, as that term is used in Article 3(2) of the Prospectus Directive, (1) the securities acquired by it in the offer have not been acquired on behalf of, nor have they been acquired with a view to their offer or resale to, persons in any Relevant Member State other than qualified investors, as that term is defined in the Prospectus Directive, or in circumstances in which the prior consent of the representative of the underwriters has been given to the offer or resale; or (2) where securities have been acquired by it on behalf of persons in any Relevant Member State other than qualified investors, the offer of those securities to it is not treated under the Prospectus Directive as having been made to such persons.

For the purposes of the provisions in the two immediately preceding paragraphs, the expression an "offer of the securities to the public" in relation to the securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, and the expression "Prospectus Directive" means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

*Electronic Offer, Sale and Distribution of Securities.* A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The underwriters may agree to allocate an amount of securities to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

*Other Relationships.* Certain of the underwriters and their affiliates have provided, and may in the future provide, various investment banking, commercial banking and other financial services for us and our affiliates for which they have received, and may in the future receive, customary fees. Cowen and Company, LLC served as a co-placement agent for the Company's private placement offering of securities in November 2011 pursuant to an engagement letter dated June 3, 2011, as amended October 13, 2011. In connection with such offering, Cowen and Company, LLC received warrants to purchase common stock of the Company. Other than the foregoing, Cowen and Company, LLC does not have any material relationship with us or any of our officers, directors or controlling persons, except with respect to Cowen and Company, LLC's contractual relationship with us entered into in connection with this offering.

## **EXPERTS**

The consolidated financial statements of Access for the years ended December 31, 2011 and 2010 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 included 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. Legal matters in connection with the offering will be passed upon for the underwriters by Blank Rome LLP.

## **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 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, 2011 and 2010, 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, 2011 and 2010, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

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

/s/ WHITLEY PENN LLP

Dallas, Texas  
March 23, 2012

**Access Pharmaceuticals, Inc. and Subsidiaries**

CONSOLIDATED BALANCE SHEETS

ASSETS

	December 31, 2011	December 31, 2010
Current assets		
Cash and cash equivalents	\$ 2,460,000	\$ 7,033,000
Receivables	333,000	1,018,000
Inventory	151,000	-
Restricted cash	330,000	-
Prepaid expenses and other current assets	39,000	70,000
Total current assets	3,313,000	8,121,000
Property and equipment, net	51,000	32,000
Patents, net	362,000	574,000
Other assets	59,000	44,000
Total assets	\$ 3,785,000	\$ 8,771,000

LIABILITIES AND STOCKHOLDERS' DEFICIT

Current liabilities		
Accounts payable	\$ 1,713,000	\$ 2,984,000
Accrued expenses	857,000	857,000
Dividends payable	6,487,000	4,443,000
Accrued interest payable	98,000	126,000
Debt, current portion	2,750,000	5,500,000
Current portion of deferred revenue	285,000	347,000
Total current liabilities	12,190,000	14,257,000
Derivative liability - warrants	1,507,000	5,087,000
Derivative liability - preferred stock	4,430,000	5,840,000
Long-term deferred revenue	3,264,000	4,382,000
Total liabilities	21,391,000	29,566,000

Commitments and contingencies

Stockholders' deficit

Convertible preferred stock - \$.01 par value; authorized 2,000,000 shares; 2,938.3617 issued at December 31, 2011; 2,978.3617 issued at December 31, 2010		
Common stock - \$.01 par value; authorized 100,000,000 shares; issued 23,890,787 at December 31, 2011; issued 19,115,010 at December 31, 2010	-	-
Additional paid-in capital	239,000	191,000
Treasury stock, at cost – 163 shares	237,600,000	230,153,000
Accumulated deficit	(4,000)	(4,000)
Total stockholders' deficit	(255,441,000)	(251,135,000)

Total liabilities and stockholders' deficit	<u>\$ 3,785,000</u>	<u>\$ 8,771,000</u>
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The accompanying notes are an integral part of these consolidated statements.

**Access Pharmaceuticals, Inc. and Subsidiaries**

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the year ended December 31,	
	2011	2010
Revenues		
License revenues	\$ 1,181,000	\$ 347,000
Product sales	548,000	8,000
Royalties	89,000	76,000
Sponsored research and development	30,000	50,000
Total revenues	1,848,000	481,000
Expenses		
Research and development	4,200,000	3,349,000
Product costs	1,216,000	140,000
General and administrative	4,075,000	4,511,000
Depreciation and amortization	233,000	238,000
Total expenses	9,724,000	8,238,000
Loss from operations	(7,876,000)	(7,757,000)
Interest and miscellaneous income	1,334,000	2,046,000
Interest and other expense	(963,000)	(607,000)
Gain on change in fair value of derivative-warrants	3,580,000	4,621,000
Gain (loss) on change in fair value of derivative- preferred stock	1,410,000	(5,840,000)
	5,361,000	220,000
Net loss before state income taxes	(2,515,000)	(7,537,000)
State income taxes	17,000	-
Net loss	(2,532,000)	(7,537,000)
Less preferred stock dividends	(1,774,000)	(1,791,000)
Net loss allocable to common stockholders	\$ (4,306,000)	\$ (9,328,000)
Basic and diluted loss per common share		
Net loss allocable to common stockholders	\$ (0.22)	\$ (0.60)
Weighted average basic and diluted common shares outstanding	19,983,210	15,633,110

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

**Access Pharmaceuticals, Inc. and Subsidiaries**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT**

	<u>Common Stock</u>		<u>Preferred Stock</u>		Additional paid-in <u>capital</u>	Notes receivable from <u>stockholders</u>	Treasury <u>stock</u>	Accumulated <u>deficit</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
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	19,115,000	191,000	2,978.3617	-	230,153,000	-	(4,000)	(251,135,000)
Restricted common stock issued for services	98,000	1,000	-	-	202,000	-	-	-
Common stock issued for services	172,000	2,000	-	-	380,000	-	-	-
Warrants issued for services	-	-	-	-	17,000	-	-	-
Preferred stock converted into common stock	216,000	2,000	(40.0000)	-	(2,000)	-	-	-
Common stock issued for preferred dividends	1,000	-	-	-	1,000	-	-	-
Stock option compensation expense	-	-	-	-	1,066,000	-	-	-
Common stock issued \$1.45 share, net of costs	4,289,000	43,000	-	-	5,783,000	-	-	-
Preferred dividends	-	-	-	-	-	-	-	(1,774,000)
Net loss	-	-	-	-	-	-	-	(2,532,000)
Balance, December 31, 2011	<u>23,891,000</u>	<u>\$ 239,000</u>	<u>2,938.3617</u>	<u>\$ -</u>	<u>\$ 237,600,000</u>	<u>\$ -</u>	<u>\$ (4,000)</u>	<u>\$ (255,441,000)</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,	
	2011	2010
Cash flows from operating activities:		
Net loss	\$ (2,532,000)	\$ (7,537,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on change in fair value of derivative- warrants	(3,580,000)	(4,621,000)
(Gain) loss on change in fair value of derivative- preferred stock	(1,410,000)	5,840,000
Gain on negotiated payables	(1,324,000)	(509,000)
Depreciation and amortization	233,000	238,000
Stock option compensation expense	1,066,000	1,015,000
Stock and warrants issued for services	602,000	925,000
Change in operating assets and liabilities:		
Receivables	685,000	(982,000)
Inventory	(151,000)	-
Prepaid expenses and other current assets	31,000	(28,000)
Restricted cash	(330,000)	-
Other assets	(15,000)	17,000
Accounts payable and accrued expenses	53,000	(601,000)
Dividends payable	271,000	168,000
Accrued interest payable	(28,000)	(437,000)
Deferred revenue	(1,180,000)	(348,000)
Net cash used in operating activities	(7,609,000)	(6,860,000)
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:		
Payment of debt	(2,750,000)	-
Proceeds from exercise of stock options	-	192,000
Proceeds from common stock issuances, net of costs	5,826,000	13,101,000
Net cash provided by financing activities	3,076,000	13,293,000
Net increase (decrease) in cash and cash equivalents	(4,573,000)	6,426,000
Cash and cash equivalents at beginning of year	7,033,000	607,000
Cash and cash equivalents at end of year	\$ 2,460,000	\$ 7,033,000
<i>Supplemental cash flow information:</i>		
Cash paid for interest	\$ 720,000	\$ 874,000
<i>Supplemental disclosure of noncash transactions</i>		
Shares issued for dividends on preferred stock	1,000	288,000
Warrants issued for placement agent fees	39,000	274,000
Preferred stock dividends in dividends payable	1,774,000	1,791,000

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, 2011

#### 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 evaluation 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, 2011 and 2010, we had no such investments. We maintain deposits primarily in two financial institutions, which may at times exceed amounts covered by insurance provided by the U.S. Federal Deposit Insurance Corporation (FDIC). We have not experienced any losses related to amounts in excess of FDIC limits.

##### Receivables

Receivables are reported in the balance sheets at the outstanding amount net of an allowance for doubtful accounts. We continually evaluate the creditworthiness of our customers and their financial condition and generally do not require collateral. The allowance for doubtful accounts is based upon reviews of specific customer balances, historic losses, and general economic conditions. As of December 31, 2011 and 2010, no allowance was recorded as all accounts are considered collectible.

### Property and Equipment

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

### 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, 2011 and 2010, 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 38,854,446 and 25,784,976 were excluded from the loss per share computation for 2011 and 2010, 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, 2011</u>		<u>December 31, 2010</u>	
	<u>Gross carrying value</u>	<u>Accumulated amortization</u>	<u>Gross carrying value</u>	<u>Accumulated amortization</u>
Amortizable intangible assets - Patents				
	<u>\$ 2,624</u>	<u>\$ 2,262</u>	<u>\$ 2,624</u>	<u>\$ 2,050</u>

Amortization expense related to intangible assets totaled \$212,000 and \$213,000 for the years ended December 31, 2011 and 2010, respectively. The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2011 is as follows (in thousands):

2012	\$	82
2013		44
2014		44
2015		44
2016		44
Thereafter		<u>104</u>
Total	\$	<u>362</u>

### Revenues

Our revenues are generated from licensing, research and development agreements, royalties and product sales. We recognize revenue in accordance with SEC Staff Accounting Bulletin No. 104 (SAB 104), *Revenue Recognition*. License revenue is recognized over the remaining life of the underlying patent. Research and development revenues are recognized as services are performed. Royalties are recognized in the period of sales. We recognize revenue for MuGard product sales at the time title transfers to our customers, which occurs at the time product is delivered to our customers.

### 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 \$541,000 in 2010 and recorded the remaining \$938,000 in receivables at December 31, 2010. We received payment of \$938,000 in 2011. In 2011 and 2010, we recognized miscellaneous income of \$1,324,000 and \$520,000, respectively, due to negotiated payables and write-offs of other accounts payable.

### Product costs

We recognize all product costs, costs of goods sold, logistics, sales and marketing and samples at the time incurred.

### 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 2011 and 2010, 580,000 stock options and 640,000 stock options, respectively, were granted under the 2005 Equity Incentive Plan. Assumptions for 2011 and 2010 are:

	<u>2011</u>	<u>2010</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.	117%	123%
Risk-free interest rate assumption is based upon U.S. Treasury bond interest rates appropriate for the term of the our employee stock options.	1.42%	2.32%
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.	5.6 years	5.7 years

At December 31, 2011, 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 \$846,000. The weighted-average period over which the unearned stock-based compensation is expected to be recognized is approximately three years. We anticipate that we will grant additional share-based awards to employees in the future, which will increase our stock-based compensation expense by the additional unearned compensation resulting from these grants.

The following table summarizes stock-based compensation for the years ended December 31, 2011 and 2010 which was allocated as follows (in thousands):

	Year ended December 31, 2011	Year ended December 31, 2010
Research and development	\$ 483	\$ 678
General and administrative	583	337
Stock-based compensation expense included in operating expense	<u>1,066</u>	<u>1,015</u>
Total stock-based compensation expense	1,066	1,015
Tax benefit	-	-
Stock-based compensation expense, net of tax	<u>\$ 1,066</u>	<u>\$ 1,015</u>

#### Recent Accounting Pronouncements

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. Upon adoption, we will have the option to report total comprehensive income, including components of net income and components of other comprehensive income, as a single continuous statement or in two separate but consecutive statements. We do not anticipate the adoption of this guidance will have a material impact on our financial statements.

#### **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, 2011 and 2010.

Management believes that our current cash and expected license fees should fund our expected burn rate into the third quarter of 2012. We are a party to a \$2.75 million promissory note due on September 13, 2012. 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

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 44.1% of the voting securities of Access. During 2011 and 2010, SCO and affiliates charged \$300,000 each year in investor relations fees.

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

Dr. Esteban Cvitkovic, a 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:

Year	Consulting Fees	Expense Reimbursement	Fair Value of Restricted Stock
2011	\$ 139,000	\$ 14,000	\$ 71,000
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 and none in 2011. Dr. Ahn's 2010 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

### NOTE 4 - PROPERTY AND EQUIPMENT

Property and equipment consists of the following:

	December 31,	
	2011	2010
Laboratory equipment	\$ 816,000	\$ 788,000
Laboratory and building improvements	6,000	58,000
Furniture and equipment	63,000	56,000
	<u>885,000</u>	<u>902,000</u>
Less accumulated depreciation and amortization	834,000	870,000
Property and equipment, net	<u>\$ 51,000</u>	<u>\$ 32,000</u>

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Depreciation and amortization on property and equipment was \$21,000 and \$25,000 for the years ended December 31, 2011 and 2010, 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 both 2011 and 2010) and to have the amount of such reduction contributed to the 401(k) Plan. We had a 401(k) matching program whereby we contributed for each dollar a participant contributes a like amount, with a maximum contribution of 4% of a participant's earnings in the first eleven months of 2011. The Company suspended matching for the year ended December 31, 2010 and again on December 1, 2011. The 401(k) Plan is intended to qualify under Section 401 of the Internal Revenue Code so that contributions by employees or by us to the 401(k) Plan, and income earned on 401(k) Plan contributions, are not taxable to employees until withdrawn from the 401(k) Plan, and so that contributions by us, if any, will be deductible by us when made. At the direction of each participant, we invest the assets of the 401(k) Plan in any of 85 investment options. Company contributions under the 401(k) Plan were approximately \$40,000 in 2011 and \$0 in 2010.

## NOTE 6 – DEBT

We have a note payable of \$2,750,000 which is due on September 13, 2012. The note bears interest at 12.0% per annum with \$330,000 of interest due on September 13<sup>th</sup>. The interest due of \$330,000 is in an escrow account for the note holder. If the note is not extended we will have to repay the note on the due date.

## NOTE 7 – COMMITMENTS AND CONTINGENCIES

### Operating Leases

At December 31, 2011, we had commitments under non-cancelable operating leases for our Dallas office and research and development facilities until December 31, 2012 totaling \$77,000. We had commitments under non-cancelable operating leases for our New York office until August 31, 2012 totaling \$130,000. Rent expense for the years ended December 31, 2011 and 2010 was \$266,000 and \$110,000, respectively. We also have one non-cancelable operating lease – for a copier with future obligations totaling approximately \$30,000 ending in 2014.

### 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, 2011 and December 31, 2010 are summarized below:

(in thousands)

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

(in thousands)

Description	As of				Total Gains (Losses)
	December 31, 2010	Level 1	Level 2	Level 3	
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 December 31, 2011, 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 November 10, 2011, we issued common stock in a private placement offering at \$1.45 per share. Per the terms of the agreement with the outstanding Series A Preferred Stock holders their stock is now converted into shares of common stock at \$1.45 per share. The Series A Preferred Stock at December 31, 2011 was convertible into 20,264,551 shares of common stock, an increase of 8,584,715 shares of common stock from December 31, 2010.

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

#### 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 November 10, 2011, the conversion price changed to \$1.45 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 November 10, 2011 the conversion price changed to \$1.45 per share.

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

#### Derivative Liability

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

We determined that the anti-dilution provision built into the preferred shares and warrants issued should be considered for derivative accounting. FASB ASC 815 requires freestanding contracts that are settled in a company's own stock to be designated as an equity instrument, 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 was \$5,840,000 and at December 31, 2011 and was \$4,430,000. 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. We recorded derivative gain of \$4,621,000 for the year ended December 31, 2010 and \$3,580,000 gain for the year ended December 31, 2011.

#### 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, 2011 and December 31, 2010. 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 \$6,487,000 were accrued at December 31, 2011, plus interest. Dividends are payable semi-annually in either cash or common stock.

## **NOTE 10 – STOCKHOLDERS' EQUITY**

### Warrants

There were warrants to purchase a total of 16,175,611 shares of common stock outstanding at December 31, 2011. All warrants were exercisable at December 31, 2011. The warrants had various exercise prices and terms as follows:

Summary of Warrants	Warrants Outstanding	Exercise Price	Expiration Date
2011 November private placement (a)	2,144,656	\$ 1.67	5/10&30/14
2011 November private placement (a)	2,144,656	2.00	11/10&30/16
2011 November placement agent warrants (a)	36,893	1.67&2.00	11/10&30/16
2011 investor relations advisor (b)	12,500	2.30	4/15/14
2010 December registered direct offering (c)	930,664	\$ 3.06	12/14/15
2010 January registered direct offering (d)	1,041,432	3.00	1/26/15
2010 January placement agent warrants (d)	125,109	3.75	1/26/15
2010 investor relations advisor (e)	60,000	2.16	10/01/13
2010 investor relations advisor (f)	55,000	2.63	10/14/13
2009 investor relations advisor (g)	25,000	3.50	11/4/14
2009 investor relations advisor (h)	30,000	3.45	9/15/12
2009 business consultant (i)	60,000	2.07	7/23/14
2009 investor relations advisor (j)	50,000	6.00	8/27/12
2008 preferred stock offering (k)	499,584	2.55	2/24/14
2008 Somanta accounts payable (l)	246,753	3.50	1/04/14
		18.55-	
2008 warrants assumed on acquisition (m)	191,668	23.19	1/31/12
2008 investor relations advisor (n)	50,000	3.15	1/03/13
2008 investor relations advisor (o)	40,000	3.00	9/01/13
2008 scientific consultant (p)	200,000	3.15	1/04/12
2007 preferred stock offering (q)	3,649,880	2.55	11/10/13
2006 convertible note (r)	3,818,180	1.32	2/16/12
2006 convertible note (r)	386,364	1.32	10/24/12
2006 convertible note (r)	377,272	1.32	12/06/12
Total	<u>16,175,611</u>		

a) In connection with a private placement offering on November 10 and 30, 2011, warrants to purchase 2,144,656 shares of common stock at \$1.67 per share were issued. All of the warrants are exercisable immediately and expire two and one half years from the date of issue.

In connection with a private placement offering on November 10 and 30, 2011, additional warrants to purchase 2,144,656 shares of common stock at \$2.00 per share were issued. All of the warrants are exercisable immediately and expire five years from the date of issue.

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

b) During 2011, an investor relations advisor received warrants to purchase 12,500 shares of common stock at an exercise price of \$2.30 per share at any time until April 15, 2014, for investor relations consulting services rendered in 2011. The expense recorded for the year ended December 31, 2011 was \$17,000.

c) 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.

d) 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.

e) 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 134,000 warrants expired. Warrants to purchase 60,000 shares of common stock are outstanding at December 31, 2011.

f) 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.

g) During 2010, an investor relations advisor received warrants to purchase 25,000 shares of common stock at an exercise price of \$3.50 per share at any time until November 4, 2014, for investor relations consulting services rendered in 2010.

h) 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. The expense recorded for the year ended December 31, 2010 was \$19,000.

i) During 2009, a business consultant received warrants to purchase 150,000 shares of common stock at an exercise price of \$2.07 per share at any time until July 23, 2014, for business consulting services rendered in 2009. 60,000 of the warrants were exercisable on December 31, 2011. The remaining 90,000 warrants expired July 23, 2010 because our stock did not reach specified trading prices.

j) 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.

- k) In connection with the preferred stock offering in February 2008, warrants to purchase a total of 499,584 shares of common stock were issued. All of the warrants are exercisable immediately and expire 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 and to \$1.45 after the November 2011 placement.
- l) In connection with our acquisition of Somanta Pharmaceuticals, Inc. (Somanta) we exchanged for \$1,576,000 due to Somanta vendors, for 538,508 shares of our common stock and warrants to purchase 246,753 shares of common stock at \$3.50. The warrants expire January 4, 2014.
- m) We assumed two warrants in the Somanta acquisition with warrants in the aggregate to purchase 191,668 shares of common stock:  
-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.
- n) 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 were exercisable January 3, 2009.
- o) 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.
- p) 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 January 4, 2010.
- q) 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 and to \$1.45 after the November 2011 placement.
- r) In connection with the convertible note offerings in 2006, warrants to purchase a total of 4,581,816 shares of common stock at \$1.32 per share were issued. All of the warrants are exercisable immediately and expire six years from date of issue. On February 10, 2012 these warrants were extended an additional three years.

#### 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.

2011 Private Placement Offering – New Commn Stock and Warrants

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

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

**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 2011: dividend yield of 0%; volatility of 117%; risk-free interest rate of 1.42%; and expected lives of 5.6 years. The weighted average fair value of options granted was \$1.87 per share during 2011. The assumptions for grants in fiscal 2010 were: 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 \$2.23 per share during 2010.

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

	<u>Options</u>	Weighted- average exercise price
Outstanding options at January 1, 2010	1,435,237	\$ 1.99
Granted, fair value of \$ 2.23 per share	640,000	2.57
Exercised	(153,051)	1.26
Expired	(173,453)	3.51
Outstanding options at December 31, 2010	1,748,733	2.13

Granted, fair value of \$ 1.87 per share	580,000	2.22
Expired/forfeited	<u>(61,949)</u>	1.38
Outstanding options at December 31, 2011	<u><u>2,266,784</u></u>	2.17
Exercisable at December 31, 2011	1,737,700	2.09

The intrinsic value of options under this plan related to the outstanding and exercisable options were \$324,000 and \$324,000 at December 31, 2011, respectively. The intrinsic value of options under this plan related to the outstanding and exercisable options were \$1,063,000 and \$1,059,000, respectively at December 31, 2010.

The total intrinsic value of options exercised during 2011 was none and during 2010 was \$187,000.

Further information regarding options outstanding under the 2005 Equity Incentive Plan at December 31, 2011 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	387,000	5.0	\$ 0.64	387,000	5.0	\$ 0.64
\$1.38	245,000	8.0	\$ 1.38	245,000	8.0	\$ 1.38
\$1.90-2.79	1,220,000	9.4	\$ 2.40	739,100	9.3	\$ 2.42
\$3.00 - 7.23	<u>414,784</u>	7.0	\$ 3.39	<u>366,600</u>	6.9	\$ 3.44
	<u><u>2,266,784</u></u>			<u><u>1,737,700</u></u>		

#### 2007 Special Stock Option Plan

In January 2007 we adopted the 2007 Special Stock Option Plan and Agreement (the Plan). The Plan provides for the award of options to purchase 450,000 shares of the authorized but unissued shares of common stock of the Company. At December 31, 2011, 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, 2011, there were no additional shares available for grant under the 1995 Stock Awards Plan. A total of 57,500 options were outstanding under this plan at December 31, 2011.

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

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

	Options	Weighted average exercise price
Outstanding options at January 1, 2010	103,000	\$ 15.89
Expired	<u>(43,500)</u>	14.65
Outstanding options at December 31, 2010	59,500	16.80
Expired	<u>(2,000)</u>	23.05
Outstanding options at December 31, 2011	<u><u>57,500</u></u>	16.58
Exercisable at December 31, 2011	57,500	16.58





There was no intrinsic value related to outstanding or exercisable options under this plan at December 31, 2011 or 2010.

Further information regarding options outstanding under the 1995 Stock Awards Plan at December 31, 2011 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	3.1	\$ 11.09	29,000	3.1	\$ 11.09
\$14.05 - 18.65	18,000	1.0	\$ 18.14	18,000	1.0	\$ 18.14
\$28.50 - 29.25	10,500	3.0	\$ 29.07	10,500	3.0	\$ 29.07
	<u>57,500</u>			<u>57,500</u>		

## NOTE 12 - INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

	2011	2010
Income taxes at U.S. statutory rate	\$ (861,000)	\$ (2,563,000)
State taxes	17,000	-
Current year reserve	857,000	3,033,000
Benefit of foreign losses not recognized	-	30,000
Expenses not deductible	4,000	(500,000)
Total tax expense	<u>\$ 17,000</u>	<u>\$ -</u>

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

	December 31,	
	2011	2010
Deferred tax assets		
Net operating loss carryforwards	\$ 63,830,000	\$ 62,760,000
General business credit carryforwards	2,439,000	2,315,000
State credits	3,097,000	3,101,000
Property and equipment	46,000	49,000
Stock options	1,480,000	1,118,000
Derivatives	2,018,000	3,715,000
Deferred revenue	1,221,000	1,622,000
Intangible assets	415,000	409,000
Accrued interest	253,000	253,000
Other	231,000	270,000
Gross deferred tax assets	<u>75,030,000</u>	<u>75,612,000</u>
Valuation allowance	<u>(75,030,000)</u>	<u>(75,612,000)</u>
Net deferred taxes	<u>\$ -</u>	<u>\$ -</u>

At December 31, 2011, we had approximately \$187,735,000 of net operating loss carryforwards and approximately \$2,439,000 of general business credit carryforwards. During 2011, net operating loss carryforwards and general business credits of \$4,232,000 expired. These carryforwards expire as follows:

	Net operating loss carryforwards	General business credit carryforwards
2012	\$ 4,212,000	\$ 77,000
2013	-	-
2014	-	-
2015	-	-
Thereafter	<u>183,523,000</u>	<u>2,362,000</u>
	<u>\$ 187,735,000</u>	<u>\$ 2,439,000</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, 2011 and 2010, 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.

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Balance Sheets

	March 31, 2012	December 31, 2011
ASSETS	(unaudited)	
Current assets		
Cash and cash equivalents	\$ 1,365,000	\$ 2,460,000
Receivables	934,000	333,000
Inventory	97,000	151,000
Restricted cash	330,000	330,000
Prepaid expenses and other current assets	43,000	39,000
Total current assets	2,769,000	3,313,000
Property and equipment, net	59,000	51,000
Patents, net	313,000	362,000
Other assets	55,000	59,000
Total assets	\$ 3,196,000	\$ 3,785,000
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities		
Accounts payable	\$ 1,878,000	\$ 1,713,000
Accrued expenses	857,000	857,000
Dividends payable	7,000,000	6,487,000
Accrued interest payable	181,000	98,000
Debt	2,750,000	2,750,000
Current portion of deferred revenue	239,000	285,000
Total current liabilities	12,905,000	12,190,000
Derivative liability - warrants	766,000	1,507,000
Derivative liability - preferred stock	6,890,000	4,430,000
Long-term deferred revenue	2,798,000	3,264,000
Total liabilities	23,359,000	21,391,000
Commitments and contingencies		
Stockholders' deficit		
Convertible Series A preferred stock - \$.01 par value; authorized		
2,000,000 shares; 2,938.3617 shares issued at March 31, 2012 and 2,938.3617 shares issued at December 31, 2011	-	
Common stock - \$.01 par value; authorized 100,000,000 shares;	241,000	
issued, 24,145,488 at March 31, 2012 and 23,890,787 at December 31, 2011	240,373,000	-
Additional paid-in capital	(4,000)	
Treasury stock, at cost – 163 shares	(260,773,000)	
Accumulated deficit		239,000
Total stockholders' deficit	(20,163,000)	237,600,000
Total liabilities and stockholders' deficit	\$ 3,196,000	(4,000)
		(255,441,000)
		\$ 3,785,000

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 March 31,	
	2012	2011
Revenues		
License revenues	\$ 1,262,000	\$ 87,000
Product sales	572,000	13,000
Royalties	21,000	20,000
Sponsored research and development	-	30,000
Total revenues	1,855,000	150,000
Expenses		
Research and development	974,000	1,120,000
Product costs	537,000	92,000
General and administrative	979,000	1,026,000
Depreciation and amortization	54,000	61,000
Total expenses	2,544,000	2,299,000
Loss from operations	(689,000)	(2,149,000)
Interest and miscellaneous income	1,000	5,000
Interest and other expense	(169,000)	(167,000)
Warrant extension expense	(2,316,000)	-
Gain on change in fair value of derivative – warrants	741,000	1,235,000
Loss on change in fair value of derivative – preferred stock	(2,460,000)	(823,000)
	(4,203,000)	250,000
Net income (loss)	(4,892,000)	(1,899,000)
Less preferred stock dividends	440,000	438,000
Net income (loss) allocable to common stockholders	\$ (5,332,000)	\$ (2,337,000)
Net income (loss) per share		
Basic	\$ (0.22)	\$ (0.12)
Diluted	\$ (0.22)	\$ (0.12)
Weighted average number of common shares outstanding		
Basic	24,145,488	19,241,570
Diluted	24,145,488	19,241,570

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, 2011	23,891,000	\$ 239,000	2,938.3617	\$ -	\$ 237,600,000	\$ (4,000)	\$(255,441,000)
Restricted common stock issued for services	15,000	-	-	-	21,000	-	-
Common stock issued for services	6,000	-	-	-	9,000	-	-
Common stock issued to directors and employees	222,000	2,000	-	-	300,000	-	-
Common stock issued for preferred dividends	11,000	-	-	-	13,000	-	-
Stock option compensation expense	-	-	-	-	114,000	-	-
Warrant extension expense	-	-	-	-	2,316,000	-	-
Preferred dividends	-	-	-	-	-	-	(440,000)
Net loss	-	-	-	-	-	-	(4,892,000)
Balance at March 31, 2012	<u>24,145,000</u>	<u>\$ 241,000</u>	<u>2,938.3617</u>	<u>\$ -</u>	<u>\$ 240,373,000</u>	<u>\$ (4,000)</u>	<u>\$(260,773,000)</u>

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Cash Flows  
(unaudited)

	Three Months ended March	
	31,	
	<u>2012</u>	<u>2011</u>
Cash flows from operating activities:		
Net loss	\$ (4,892,000)	\$ (1,899,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Gain on change in fair value of derivative - warrants	(741,000)	(1,235,000)
Loss on change in fair value of derivative - preferred stock	2,460,000	823,000
Warrant extension expense	2,316,000	-
Depreciation and amortization	54,000	61,000
Stock option compensation expense	114,000	181,000
Stock issued to directors and employees	302,000	-
Stock issued for services	30,000	246,000
Change in operating assets and liabilities:		
Receivables	(601,000)	972,000
Inventory	54,000	-
Prepaid expenses and other current assets	(4,000)	21,000
Other assets	4,000	4,000
Accounts payable and accrued expenses	165,000	(92,000)
Dividends payable	86,000	61,000
Accrued interest payable	83,000	106,000
Deferred revenue	(512,000)	(86,000)
Net cash used in operating activities	<u>(1,082,000)</u>	<u>(837,000)</u>
Cash flows from investing activities:		
Capital expenditures	<u>(13,000)</u>	<u>(22,000)</u>
Net cash used in investing activities	<u>(13,000)</u>	<u>(22,000)</u>
Net increase (decrease) in cash and cash equivalents	(1,095,000)	(859,000)
Cash and cash equivalents at beginning of period	<u>2,460,000</u>	<u>7,033,000</u>
Cash and cash equivalents at end of period	<u>\$ 1,365,000</u>	<u>\$ 6,174,000</u>
<i>Supplemental cash flow information:</i>		
Cash paid for interest	\$ -	\$ -
<i>Supplemental disclosure of noncash transactions:</i>		
Shares issued for dividends on preferred stock	13,000	1,000
Preferred stock dividends in dividends payable	\$ 440,000	\$ 438,000

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

## Access Pharmaceuticals, Inc. and Subsidiaries

### Notes to Condensed Consolidated Financial Statements Three Months Ended March 31, 2012 and 2011 (unaudited)

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 and medical device products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies.

#### (1) Interim Financial Statements

The condensed consolidated balance sheet as of March 31, 2012, the condensed consolidated statements of operations for the three months ended March 31, 2012 and 2011, the condensed consolidated statements of stockholders deficit for the three months ended March 31, 2012, and the condensed consolidated statements of cash flows for the three months ended March 31, 2012 and 2011, 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, 2011. The results of operations for the period ended March 31, 2012 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, 2011 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, 2011, 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 therein and in this Quarterly Report on Form 10-Q. 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):

<u>March 31, 2012</u>		<u>December 31, 2011</u>	
Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated Amortization
Amortizable intangible			

assets

Patents	\$	2,624	\$	2,311	\$	2,624	\$	2,262
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Amortization expense related to intangible assets totaled \$49,000 for the three months ended March 31, 2012 and totaled \$53,000 for the three ended March 31, 2011. The aggregate estimated amortization expense for intangible assets remaining as of March 31, 2012 is as follows (in thousands):



2012	\$	33
2013		44
2014		44
2015		44
2016		44
over 5 years		<u>104</u>
Total	\$	<u><u>313</u></u>

### **(3) Note Payable**

As of March 31, 2012, we had one secured note outstanding in the principal amount of \$2,750,000. The note is due on September 13, 2012.

### **(4) Liquidity**

The Company generated net loss allocable to common stockholders of \$5,332,000 for the three months ended March 31, 2012 and a loss of \$4,306,000 for the year ended December 31, 2011. At March 31, 2012, our working capital deficit was \$10,136,000. As of March 31, 2012, we had one secured note outstanding in the principal amount of \$2,750,000. The note is due on September 13, 2012. Management believes that our current cash, revenues from MuGuard sales and expected license fees should fund our expected burn rate into the third quarter of 2012. 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 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 March 31, 2012 and December 31, 2011 are summarized below:

(in thousands)

Description	As of March 31, 2012	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability- warrants	\$ 766	\$ -	\$ 766	\$ -	\$ 741
preferred stock	\$ 6,890	\$ -	\$ -	\$ 6,890	\$ (2,460)

(in thousands)

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

In order to calculate the Level 3 Derivative liability - preferred stock, we used the Monte Carlo simulation to estimate future stock prices. The use of valuation techniques requires the Company to make various key assumptions for inputs into the model, including assumptions about the expected future volatility of the price of the Company's stock. In estimating the fair value at March 31, 2012 and December 31, 2011, 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 months ended March 31, 2012, we recognized stock-based compensation expense of \$114,000. For the three months ended March 31, 2011 we recognized stock-based compensation expense of \$181,000.

The following table summarizes stock-based compensation for the three months ended March 31, 2012 and 2011:

	Three months ended March 31,	
	2012	2011
Research and development	\$ 73,000	\$ 103,000
General and administrative	41,000	78,000
Stock-based compensation expense included in operating expense	\$ 114,000	\$ 181,000

For the three months ended March 31, 2012 we granted no stock options. For the three months ended March 31, 2011 we granted 100,000 stock options.

Our weighted average Black-Scholes fair value assumptions used to value the grants made in the first three months of 2012 and 2011 are as follows:

	<u>3/31/12</u>		<u>3/31/11</u>	
Expected life <sup>(b)</sup>	0 yrs		6.25 yrs	
Risk free interest rate	0.0	%	1.1	%
Expected volatility <sup>(a)</sup>	0.0	%	112	%
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.

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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**

**Shares of Common Stock**  
**Warrants to Purchase up to                      Shares of Common Stock**

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**PROSPECTUS**

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**Cowen and Company**

\_\_\_\_\_, 2012

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution**

Expenses of the Registrant in connection with the issuance and distribution of the securities being registered, are estimated as follows:

SEC Registration Fee	\$ _____
Printing and Engraving Expenses	\$ _____
Legal Fees and Expenses	\$ _____
Accountants' Fees and Expenses	\$ _____
Miscellaneous Costs	\$ _____
Total	\$ _____

**Item 14. Indemnification of Directors and Officers**

Section 145 of the Delaware General Corporation law empowers a Delaware corporation to indemnify its officers and directors and certain other persons to the extent and under the circumstances set forth therein.

The our Certificate of Incorporation, as amended, and By-laws, as amended, provide for indemnification of our officers and directors and certain other persons against liabilities and expenses incurred by any of them in certain stated proceedings and under certain stated conditions.

The above discussion of the Registrant's Certificate of Incorporation, as amended, By-laws, as amended, and Section 145 of the Delaware General Corporation Law is not intended to be exhaustive and is qualified in its entirety by such Certificate of Incorporation, By-Laws and statute.

**Item 15: Recent Sales of Unregistered Securities**

In April 2012, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In March 2012, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In February 2012, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In January 2012, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In December 2011, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

On November 30, 2011, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 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). Proceeds, net of issuance costs from the sale were \$834,000.





On November 1, 2011, we entered into securities purchase agreements (the “Purchase Agreements”) with accredited investors whereby we agreed to sell 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). Proceeds, net of issuance costs from the sale were \$5,038,000. The placement agents were granted 36,893 warrants (consisting of 18,447 warrants to purchase common stock at an exercise price of \$1.67 per share exercisable for five years and 18,446 warrants to purchase common stock at an exercise price of \$2.00 per share exercisable for five years).

In November 2011, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In October 2011, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In September 2011, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In August 2011, we issued 5,000 shares of our common stock to a consultant as payment for his consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In July 2011, we issued 105,000 shares of our common stock to several consultants as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In June 2011, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In May 2011, we issued 5,000 shares of our common stock to a consultant as payment for his consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In April 2011, we issued 80,000 shares of our common stock to several consultants as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In March 2011, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In February 2011, we issued 5,000 shares of our common stock to a consultant as payment for his consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In January 2011, we issued 55,000 shares of our common stock to several consultants as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In December 2010, we issued 38,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In November 2010, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In October 2010, we issued 67,500 shares of our common stock to several consultants as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In September 2010, we issued 51,543 shares of our common stock to several consultants as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In August 2010, we issued 60,500 shares of our common stock to several consultants as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In July 2010, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In June 2010, we issued 95,000 shares of our common stock to several consultants as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In May 2010, we issued 5,000 shares of our common stock to a consultant as payment for their consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In January 2010 thru August 2010, we issued 16,664 shares of our common stock to an employee for their employment agreement. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

In January 2010, we issued 66,667 shares of our common stock to a consultant for his consulting expenses. The issuance of shares of our common stock in settlement of these accounts was made pursuant to Section 4(2) and Rule 506 of the Securities Act of 1933, as amended.

All of the above-described issuances were exempt from registration pursuant to Section 4(2) of the Securities Act or Rule 506 of Regulation D promulgated thereunder, as transactions not involving a public offering.

## **Item 16. Exhibits**

The following is a list of exhibits filed as a part of this registration statement:

### Exhibit

#### Number    Description of Document

- 1.1    Form of Underwriting Agreement (to be filed by amendment)

- 2.1 Amended and Restated Agreement of Merger and Plan of Reorganization between the Registrant and Chemex Pharmaceuticals, Inc., dated as of October 31, 1995 (Incorporated by reference to Exhibit A of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
- 2.2 Agreement and Plan of Merger, by and among the Registrant, Somanta Acquisition Corporation, Somanta Pharmaceuticals, Inc., Somanta Incorporated and Somanta Limited, dated April 19, 2007 (Incorporated by reference to Exhibit 2.1 to our Form 8-K dated April 18, 2007)
- 2.3 Agreement and Plan of Merger, by and among the Registrant, MACM Acquisition Corporation and MacroChem Corporation, dated July 9, 2008 (Incorporated by reference to Exhibit 2.3 of our Form 10-Q for the quarter ended June 30, 2008)
- 3.1 Certificate of Incorporation (Incorporated by reference to Exhibit 3(a) of our Form 8-K dated July 12, 1989, Commission File Number 9-9134)
- 3.2 Certificate of Amendment of Certificate of Incorporation filed August 13, 1992 (Incorporated by reference to Exhibit 3.3 of our Form 10-K for year ended December 31, 1995)
- 3.3 Certificate of Merger filed January 25, 1996 (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
- 3.4 Certificate of Amendment of Certificate of Incorporation filed January 25, 1996 (Incorporated by reference to Exhibit E of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
- 3.5 Certificate of Amendment of Certificate of Incorporation filed July 18, 1996 (Incorporated by reference to Exhibit 3.7 of our Form 10-K for the year ended December 31, 1996)
- 3.6 Certificate of Amendment of Certificate of Incorporation filed June 18, 1998. (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended June 30, 1998)
- 3.7 Certificate of Amendment of Certificate of Incorporation filed July 31, 2000 (Incorporated by reference to Exhibit 3.8 of our Form 10-Q for the quarter ended March 31, 2001)
- 3.8 Certificate of Designations of Series A Junior Participating Preferred Stock filed November 7, 2001 (Incorporated by reference to Exhibit 4.1.H of our Registration Statement on Form S-8 dated December 14, 2001, Commission File No. 333-75136)
- 3.9 Amended and Restated Bylaws (Incorporated by reference to Exhibit 2.1 of our Form 10-Q for the quarter ended June 30, 1996)
- 3.10 Certificate of Designation, Rights and Preferences of Series A Cumulative Convertible Preferred Stock filed November 9, 2007 (Incorporated by reference to Exhibit 3.10 to our Form SB-2 filed on December 10, 2007.
- 3.11 Certificate of Amendment to Certificate of Designations, Rights and Preferences of Series A Cumulative Convertible Preferred Stock filed June 11, 2008 (Incorporated by reference to Exhibit 3.11 of our Form 10-Q for the quarter ended June 30, 2008)
- 4.1 Form of Common Stock Purchase Warrant (to be filed by amendment)
- 4.2 Form of Representative's Warrant to be issued to Cowen and Company, LLC (to be filed by amendment)
- 5.1 Opinion of Bingham McCutchen LLP (to be filed by amendment)
- 10.1\* 1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form S-4 dated December 20, 1995, Commission File No. 33-64031)
- 10.2\* Amendment to 1995 Stock Option Plan (Incorporated by reference to Exhibit 10.25 of our Form 10-K for the year ended December 31, 2001)
- 10.3 Lease Agreement between Pollock Realty Corporation and the Registrant dated July 25, 1996 (Incorporated by reference to Exhibit 10.19 of our Form 10-Q for the quarter ended September 30, 1996)
- 10.4 Platinate HPMA Copolymer Royalty Agreement between The School of Pharmacy, University of London and the Registrant dated November 19, 1996 (Incorporated by reference to Exhibit 10.9 of our Form 10-K for the year ended December 31, 1996)
- 10.5\* 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10-K for the year ended December 31, 1999)
- 10.6\* 2005 Equity Incentive Plan (Incorporated by reference to Exhibit 1 of our Proxy Statement filed on April 18, 2005)
- 10.7 Asset Sale Agreement dated as of October 12, 2005, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.25 of our 10-K for the year ended December 31, 2005)

- 10.8 Amendment to Asset Sale Agreement dated as of December 8, 2006, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.16 of our Form 10-KSB filed on April 2, 2007)
- 10.9 License Agreement dated as of October 12, 2005, between the Registrant and Uluru, Inc. (Incorporated by reference to Exhibit 10.26 of our 10-K for the year ended December 31, 2005)
- 10.10 Form of Warrant dated February 16, 2006, issued by the Registrant to certain Purchasers (Incorporated by reference to Exhibit 10.31 of our Form 10-Q for the quarter ended March 31, 2006)
- 10.11 Form of Warrant dated October 24, 2006, issued by the Registrant to certain Purchasers (Incorporated by reference to Exhibit 10.27 of our Form 10-KSB filed on April 2, 2007)
- 10.12 Form of Warrant December 6, 2006, issued by the Registrant to certain Purchasers (Incorporated by reference to Exhibit 10.32 of our Form 10-KSB filed on April 2, 2007)
- 10.13\* 2007 Special Stock Option Plan and Agreement dated January 4, 2007, by and between the Registrant and Stephen R. Seiler, President and Chief Executive Officer (Incorporated by reference to Exhibit 10.35 of our Form 10-QSB filed on May 15, 2007)
- 10.14 Note Purchase Agreement dated April 26, 2007, between the Registrant and Somanta Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.42 of our Form 10-Q filed on August 14, 2007)
- 10.15 Preferred Stock and Warrant Purchase Agreement, dated November 7, 2007, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.23 of our Form S-1 filed on March 11, 2008)
- 10.16 Investor Rights Agreement dated November 10, 2007, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.24 of our Form S-1 filed on March 11, 2008)
- 10.17 Form of Warrant Agreement dated November 10, 2007, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.25 of our Form S-1 filed on March 11, 2008)
- 10.18 Board Designation Agreement dated November 15, 2007, between the Registrant and SCO Capital Partners LLC (Incorporated by reference to Exhibit 10.26 of our Form S-1 filed on March 11, 2008)
- 10.19 Amendment and Restated Purchase Agreement, dated February 4, 2008 between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.27 of our Form S-1 filed on March 11, 2008)
- 10.20 Amended and Restated Investor Rights Agreement, dated February 4, 2008, between the Registrant and certain Purchasers (Incorporated by reference to Exhibit 10.28 of our Form S-1 filed on March 11, 2008)
- 10.21\* Employment Agreement dated January 4, 2008, between the Registrant and Jeffrey B. Davis (Incorporated by reference to Exhibit 10.29 of our Form S-1 filed on March 11, 2008)
- 10.22 Form of Securities Purchase Agreement (Incorporated by reference to Exhibit 10.29 of our Form S-1 filed on January 15, 2010)
- 10.23 Form of Warrant (Incorporated by reference to Exhibit 10.30 of our Form S-1 filed on January 15, 2010)
- 10.24\* Employment Agreement of David P. Nowotnik, PhD (Incorporated by reference to Exhibit 10.31 of our Form 8-K February 8, 2010)
- 10.25 Form of Securities Purchase Agreement dated as of December 10, 2010 by and among us and the Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on December 14, 2010)
- 10.26 Form of Common Stock Warrant issued by us (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on December 14, 2010)
- 10.27 Form of Securities Purchase Agreement dated as of November 1, 2011 by and among us and the Purchasers named therein (Incorporated by reference to Exhibit 10.1 of our Form 8-K filed on November 10, 2011)
- 10.28 Form of Common Stock Warrant (Two and One Half Year Warrant) issued by us (Incorporated by reference to Exhibit 10.2 of our Form 8-K filed on November 10, 2011)
- 10.29 Form of Common Stock Warrant (Five Year Warrant) issued by us (Incorporated by reference to Exhibit 10.3 of our Form 8-K filed on November 10, 2011)

- 10.30 Amendment No.1 to Warrant Agreement dated February 10, 2012 by and among us and warrant holders including certain affiliates named therein extending the term of certain warrants until 2015 (Incorporated by reference to Exhibit 99.1 of our Form 8-K filed on February 10, 2012)
- 23.1 Consent of Whitley Penn LLP
- 23.2 Consent of Bingham McCutchen LLP (included in Exhibit 5.1)

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

## Item 17. Undertakings

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
  - (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
  - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
  - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the registration statement is on Form S-3 or Form S-8, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to Section 13 or Section 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

- (2) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (3) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (4) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised 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. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.







Date June 25, 2012

By: \*  
Steven H. Rouhandeh, Chairman of  
the Board

Date June 25, 2012

By: /s/ Stephen B. Thompson  
Stephen B. Thompson  
Attorney-in-fact

\* - Executed June 25, 2012 by Stephen B. Thompson as attorney-in-fact under power of attorney granted in Registration Statement previously filed on February 21, 2012.

## Exhibit

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- 10.5\* 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10-K for the year ended December 31, 1999)
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- 10.30 Amendment No.1 to Warrant Agreement dated February 10, 2012 by and among us and warrant holders including certain affiliates named therein extending the term of certain warrants until 2015 (Incorporated by reference to Exhibit 99.1 of our Form 8-K filed on February 10, 2012)
- 23.1 Consent of Whitley Penn LLP
- 23.2 Consent of Bingham McCutchen LLP (included in Exhibit 5.1)

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

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We have issued our report dated March 23, 2012, accompanying the consolidated financial statements of Access Pharmaceuticals, Inc., which is included in this Registration Statement. We consent to the inclusion in Pre-Effective Amendment No. 3 to the Registration Statement of Access Pharmaceuticals, Inc. on Form S-1 of the aforementioned report. We also consent to the reference to our firm under the heading "Experts" in such Registration Statement.

/s/ Whitley Penn LLP

Dallas, Texas  
June 25, 2012

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