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

FORM S-1 **REGISTRATION STATEMENT** UNDER THE SECURITIES ACT OF 1933

## ACCESS PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

3841 (Primary Standard Industrial

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

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

Classification Code Number)

(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)

with a copy to: John J. Concannon III, Esq. **Bingham McCutchen LLP One Federal Street** Boston, MA 02110 (617) 951-8000

Delaware (State or other jurisdiction of incorporation or organization)

#### 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.  $\Box$ 

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  $\Box$ 

Non-accelerated filer  $\Box$ 

Accelerated filer  $\Box$ 

Smaller reporting company 🗵

Proposed maximum

A mount of

### **CALCULATION OF REGISTRATION FEE**

Title of each class of securities to be registered		gate offering price	-	Amount of stration fee(1)	
Units, each unit consisting of shares of Common Stock, \$0.01 par value, and warrants to purchase shares of Common Stock	¢	25,000,000	¢	1.395	
	\$	23,000,000	φ	1,595	
Common Stock included in the Units	\$		\$	_	
Warrants included in the Units	\$			—	(3)
Common Stock issuable upon exercise of the warrants included in the Units					
(2)	\$			_	(3)
Warrants issued to placement agent	\$			_	(3)
Common Stock issuable upon exercise of placement agent warrants	\$			_	(3)
Series A Junior Participating Preferred Stock Purchase Rights (4)					
Total	\$	25,000,000	\$	1,395	

(1) Calculated pursuant to Rule 457(o) on the basis of the maximum aggregate offering price of all of the securities to be registered.

(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) This registration statement also relates to the rights to purchase shares of Series A Junior Participating Preferred Stock of the registrant, which, pursuant to the terms of the registrant's Rights Agreement dated October 31, 2001, as amended and in effect, will be attached to all shares of common stock issued until the occurrence of certain events prescribed in the Rights Agreement. The rights will not be exercisable and will be transferred with and only with shares of our common stock until the occurrence of certain events prescribed in the Rights Agreement.

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.

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 SELLAND IS NOT A SOLICITATION OF AN OFFER TO BUY IN ANY STATE IN WHICH AN OFFER, SOLICITATION, OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED \_\_\_\_\_, 2009

PROSPECTUS

#### UNITS, EACH CONSISTING OF SHARES OF COMMON STOCK AND WARRANTS

We are offering up to \_\_\_\_\_\_\_ units, each unit consisting of \_\_\_\_\_\_\_ shares of our common stock and warrants to purchase an additional \_\_\_\_\_\_\_ shares of our common stock. Each warrant entitles its holder to purchase one share of our common stock at an exercise price of \$\_\_\_\_\_\_ per share. The units will separate immediately and the common stock and warrants will be issued separately and the common stock will trade separately. We are not required to sell any specific dollar amount or number of units, but will use our best efforts to sell all of the units being offered. The offering expires on the earlier of (i) the date upon which all of the units being offered have been sold, or (ii) \_\_\_\_\_\_. We and the placement agent may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.

Our common stock is presently listed on the Over-the-counter Bulletin Board under the symbol "ACCP". We intend to apply for listing of our shares of common stock on the NYSE Amex in connection with this offering. We do not intend to apply for listing of the warrants on any securities exchange. On October 26, 2009, the last reported sale price of our common stock on the OTC BB was \$3.30 per share.

# INVESTING IN THE OFFERED SECURITIES INVOLVES RISKS, INCLUDING THOSE SET FORTH IN THE "RISK FACTORS" SECTION OF THIS PROSPECTUS BEGINNING ON PAGE 7.

Offering Price per Unit	Per Unit	Total
	\$	\$
Placement Agent's Fees	\$	\$
Offering Proceeds before expenses	\$	\$

has agreed to act as our placement agent in connection with this offering. In addition, may engage one or more sub-placement agents or selected dealers. The placement agent is not purchasing the securities offered by us, and is not required to sell any specific number or dollar amount of units, but will assist us in this offering on a "best efforts" basis. We have agreed to pay the placement agent a cash fee equal to \_\_% of the gross proceeds of the offering of units by us, as well as "placement agent warrants" to purchase shares of our common stock equal to \_\_% of the aggregate number of shares of common stock included in units sold in the offering. The placement agent warrants will have terms substantially similar to the warrants included in units offered hereby, except that the placement agent warrants will have a term of five years from a closing of the sale of units. We estimate the total expenses of this offering, excluding the placement agent fees, will be approximately \$ . Because there is no minimum offering amount required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. See "Plan of Distribution" beginning on page 73 of this prospectus for more information on this offering and the placement agent arrangements. ]

This offering will terminate on \_\_\_\_\_\_, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. All costs associated with the registration will be borne by us.

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.

The shares of Common Stock may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers. See "Plan of Distribution". If any underwriters are involved in the sale of any shares of Common Stock in respect of which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The net proceeds we expect to receive from such sale also will be set forth in a prospectus supplement.

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

THE DATE OF THIS PROSPECTUS IS \_\_\_\_\_, 2009.

PROSPECTUS SUMMARY	1
ABOUT THIS PROSPECTUS	1
ABOUT ACCESS	1
SUMMARY OF THE OFFERING	4
SUMMARY CONDENSED CONSOLIDATED FINANCIAL INFORMATION	5
RISK FACTORS	7
FORWARD-LOOKING STATEMENTS	18
USE OF PROCEEDS	19
DILUTION	20
PRICE RANGE OF OUR COMMON STOCK	21
DIVIDEND POLICY	22
SELECTED CONDENSED CONSOLIDATED FINANCIAL DATA	23
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND	
RESULTS OF OPERATIONS	29
DESCRIPTION OF BUSINESS	41
DESCRIPTION OF PROPERTY	56
DIRECTORS, EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS	57
LEGAL PROCEEDINGS	65
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	65
TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS	67
DESCRIPTION OF SECURITIES	69
PLAN OF DISTRIBUTION	73
EXPERTS	76
LEGAL MATTERS	76
WHERE YOU CAN FIND MORE INFORMATION	76
FINANCIAL STATEMENTS	F-1

# Page

#### PROSPECTUS SUMMARY

#### UNITS, EACH CONSISTING OF SHARES OF COMMON STOCK AND WARRANTS

#### **ABOUT THIS PROSPECTUS**

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

### **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 products based upon our nanopolymer chemistry technologies. We currently have one approved product, two product candidates in Phase 2 clinical trials and several product candidates in pre-clinical development. Our description of our business, including our list of products and product candidates as well as our patents, takes into consideration our acquisition of Somanta Pharmaceuticals, Inc. which closed January 4, 2008 and our acquisition of MacroChem Corporation which closed on February 25, 2009.

- MuGard<sup>™</sup> is our approved product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the Food & Drug Administration ("FDA"). MuGard has been launched in Germany, Italy, UK, Greece and the Nordic countries by our European commercial partner, SpePharm.
- Our lead development candidate for the treatment of cancer is ProLindac<sup>™</sup>, a nanopolymer DACH-platinum prodrug. We recently completed a Phase 2 clinical trial on ProLindac in the EU in patients with ovarian cancer. The clinical study had positive safety and efficacy results. We are currently planning a number of combination trials, looking at combining ProLindac with other cancer agents such as taxol and gemcitabine, in solid tumor indications including colorectal and ovarian. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which had worldwide sales in excess of \$2.0 billion in 2008.
- 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 antitumor activity. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and intend to initiate additional Phase 2 clinical trials in adult AML, ALL and other indications.
- Cobalamin<sup>TM</sup> is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We are currently developing a product for the oral delivery of insulin,, and are conducting sponsored development of a product for oral delivery of human growth hormone, in each case, based upon this technology.
- Cobalamin-mediated cancer targeted delivery is a preclinical technology which makes use of the fact that cell surface receptors for vitamins such as B12 are often overexpressed by cancer cells.

#### **Products and Product Candidates**

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

#### Access Drug Portfolio

Compound	Originator	Technology	Indication	Clinical Stage (1)
MuGard™	Access	Mucoadhesive liquid	Mucositis	(510k) Marketing clearance received
ProLindacTM (Polymer Platinate, AP5346)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Thiarabine (4-thio Ara-C)	Southern Research Institute	Small molecule	Cancer	Phase ½
Oral Insulin	Access	Cobalamin	Diabetes	Pre-clinical
Oral Delivery System	Access	Cobalamin	Various	Pre-clinical
Cobalamin-Targeted Therapeutics	Access	Cobalamin	Anti-tumor	Pre-clinical

(1) For more information, see "Government Regulation" for description of clinical stages. Some of these clinical development projects are subject to funding.

(2) Licensed from the School of Pharmacy, The University of London.

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

#### **Other Key Developments**

On October 6, 2009, we announced that we signed an agreement with iMedicor for the North American launch of MuGard. iMedicor's highly targeted Alerts System application will begin introducing MuGard by the end of the year to the 216,000 selected physicians in the Unites States.

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

On August 3, 2009, we announced that we commenced a new clinical study of ProLindac in France. The study will examine dose levels and regimens of ProLindac monotherapy in cancer patients, provide additional data to support design of combinations studies, and extend the safety database. Two ovarian cancer patients have been enrolled in the study to date, and it is anticipated 6 to 12 patients will be enrolled this year in advance of enrolling patients in trial evaluating ProLindac in combination with other chemotherapies.

On July 29, 2009, we announced that we are evaluating strategic options for the commercialization of MuGard in North America. Mr. Frank Jacobucci, formerly President & CEO of Milestone Biosciences, has joined Access as a consultant, and will assist with ongoing reimbursement, manufacturing and commercial launch activities at Access, while discussions with potential licensee and co-promotion partners is ongoing.

On July 23, 2009, we announced that our European partner, SpePharm, is collecting data from a post approval market seeding study of MuGard in head and neck cancer patients undergoing radiation treatment in the UK showing prevention of oral mucositis. In a multi-center study expected to enroll a total of 280 patients, patients are provided with seven weeks of MuGard therapy, and begin using MuGard one week prior to radiation treatment and then throughout the subsequent six weeks of planned therapy. The first 140 patients being treated in this market seeding study have been enrolled and treated, and as of the time of the update, none of these patients had experienced any oral mucositis.

On July 7, 2009, we announced new preclinical data demonstrating that thiarabine shows remarkable efficacy in the prevention and treatment of rheumatoid arthritis (RA). In a well-established animal model for RA, an exceptional restoration of joint structure was observed in the studies, which were conducted at Wayne State University School of Medicine and at Southern Research Institute.



On June 17, 2009, we announced that we signed evaluation agreements with two biopharmaceutical companies for our Cobalamin<sup>™</sup> Oral Drug Delivery Technology. Under the terms of the agreements, both companies plan to evaluate Access' oral insulin product in preclinical models as a prerequisite to entering licensing discussions.

On February 25, 2009, we closed the previously announced acquisition of MacroChem Corporation.

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

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

Steven H. Rouhandeh was appointed as a director and Chairman of the Board effective as of March 4, 2008.

On February 4, 2008, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 272.5 shares of our preferred stock, designated "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series A Cumulative Convertible Preferred Stock") and agreed to issue warrants to purchase 545,000 shares of our common stock, subject to adjustment, which includes placement agent warrants to purchase 90,883 shares of our common stock, at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Cumulative Convertible Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share, subject to adjustment.

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

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

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

### **Corporate Information**

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

#### SUMMARY OF THE OFFERING

Securities offered:	Up to units. Each unit will consist of shares of our common stock and warrants to purchase up to an additional shares of our common stock.
Offering Price:	\$ per unit.
Description of Warrants:	The warrants will include an exercise price of \$per share. We and the placement agent may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.
Common stock outstanding prior to the offering:	shares.
Common stock outstanding after the offering:	shares, which does not includeshares of common stock issuable upon exercise of the warrants included in the offered units or the shares of common stock issuable upon the exercise of the placement agent warrants.
Over-allotment option:	The placement agent will have a 30-day option to arrange for the sale of up to an additional units (consisting of shares and warrants to purchase shares of common stock) to cover over-allotments.
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.
OTC BB Symbol:	ACCP.OB
Risk Factors:	See "Risk Factors" beginning on page 7 and the other information in this prospectus for a discussion of the factors you should consider before you decide to invest in the units.
The total number of shares of our common stock outsta	nding is 12 111 545 and avaluate the following:

The total number of shares of our common stock outstanding is 13,111,545 and excludes the following:

- 1,832,184 shares of common stock reserved for future issuance under our equity incentive plans. As of October 26, 2009, there were options to purchase 1,579,904 shares of our common stock outstanding under our equity incentive plans with a weighted average exercise price of \$2.90 per share;
- 9,835,479 shares of common stock issuable upon exercise of outstanding warrants as of October 26, 2009, with exercise prices ranging from \$1.32 per share to \$69.57 per share; and
- shares of common stock that will be issued upon exercise of warrants at an exercise price of \$\_\_\_\_\_ per share sold as part of the units in this offering.
- 9,974,531 shares of our common stock initially issuable upon conversion of Series A Cumulative Convertible Preferred Stock, subject to adjustment; and
- the conversion of our currently outstanding Convertible Note.

All information in this prospectus assumes the placement agent does not sell any units contained in the 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, 2008 and 2007, have been derived from our audited financial statements. The financial information as of and for the six months ended June 30, 2009 and 2008 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.

(in thousands, except per share amounts)	For the Six Months Ended June 30,					For the Year Ended December 31.		
		2009		2008		2008		2007
Consolidated Statement of Operations Data:								
Total revenues	\$	104	\$	170	\$	291	\$	57
Operating loss		(4,051)		(25,126)		(16,915)		(6,900)
Interest and miscellaneous income		16		141		178		125
Interest and other expense		(262)		(329)		(478)		(3,514)
Loss on extinguishment of debt		-		-		-		(11,628)
Income tax benefit		-		-		-		61
Loss from continuing operations		(4,297)		(25,314)		(17,215)		(21,856)
Preferred stock dividends Discontinued operations net of taxes of		(963)		(2,350)		(3,358)		(14,908)
Discontinued operations, net of taxes of \$61 in 2007		-		-		-		112
Net loss	\$	(5,260)	\$	(27,664)	\$	(20,573)	\$	(36,652)
Common Stock Data:								
Net loss per basic and diluted common share	\$	(0.48)	\$	(3.45)	\$	(3.51)	\$	(10.32)
Weighted average basic and diluted common shares outstanding		10,954		8,008		5,854		3,552

	June 30,			December 31,				
		2009		2008		2008		2007
Consolidated Balance Sheet Data:					_			
Cash, cash equivalents and short term investments	\$	1,231	\$	5,888	\$	2,663	\$	6,921
Total assets		2,351		6,920		4,257		9,149
Deferred revenue		3,789		2,047		2,409		978
Convertible notes		5,500		5,500		5,500		5,564
Total liabilities		16,177		10,994		12,651		8,468
Total stockholders' equity (deficit)		(13,826)		(4,074)		(8,394)		681

#### MacroChem Corporation

Below is a summary of selected financial information for MacroChem Corporation. We completed our acquisition of MacroChem on February 25, 2009. Historical information from MacroChem's audited financial statements for the fiscal year ended December 31, 2008 is also contained in Access' current report on Form 8-K/A filed with the Securities and Exchange Commission on August 26, 2009. The information is only a summary and should be read in conjunction with MacroChem's financial statements referenced above and accompanying notes.

2008

\$

3,474

(2,925)

#### (in thousands, except per share amounts)

Stockholders' (deficit) equity

### CONSOLIDATED STATEMENT OF OPERATIONS DATA:

Total revenues	\$	4
Operating loss	Ψ	(13,812)
Interest and other income		(15,012)
Interest and other expense		(433)
Gain on change in value of warrants liability		3,972
Gain on sale of equipment		5,572
Net loss	\$	(10,240)
Net loss per basic and diluted common share	\$	(0.26)
Weighted average basic and diluted common shares outstanding		38,934
		,
CONSOLIDATED BALANCE SHEET DATA:		
	De	cember 31,
Cash and cash equivalents	\$	14
Total assets		549
Current liabilities		3,346
Total liabilities		3 474

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

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

We have recorded minimal revenue to date and have incurred an accumulated deficit of approximately \$134.9 million through December 31, 2008. Net losses for the years ended 2008 and 2007 were \$20.6 million and \$36.7 million, respectively. Our losses have resulted principally from costs incurred in research and development activities related to our efforts to develop clinical drug candidates and from the associated administrative costs. We expect to incur additional operating losses over the next several years. We also expect cumulative losses to increase if we expand research and development efforts and preclinical and clinical trials. Our net cash burn rate for the year ended December 31, 2008 was approximately \$505,000 per month. We project our net cash burn rate from operations for the next twelve months to be approximately \$115,000 per month. Capital expenditures are forecasted to be minor for the next twelve months.

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

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

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

To date, have had funded its operations primarily through private sales of common stock, preferred stock and convertible notes. Contract research payments and licensing fees from corporate alliances and mergers have also provided funding for its operations. Its ability to achieve significant revenue or profitability depends upon its 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 Access' drug candidates and to manufacture and commercialize the resulting drugs. Access is not expecting any significant revenues in the short-term from its products or product candidates. Furthermore, Access may not be able to ever successfully identify, develop, commercialize, patent, manufacture, obtain required regulatory approvals and market any additional products. Moreover, even if Access does identify, develop, commercialize, patent, manufacture, obtain required regulatory approvals to market additional products, Access may not generate revenues or royalties from commercial sales of these products for a significant number of years, if at all. Therefore, its proposed operations are subject to all the risks inherent in the establishment of a new business enterprise. In the next few years, its revenues may be limited to minimal product sales and royalties, any amounts that Access receives under strategic partnerships and research or drug development collaborations that Access may establish and, as a result, Access may be unable to achieve or maintain profitability in the future or to achieve significant revenues in order to fund its operations.



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

Our ability to realize the anticipated benefits of the acquisitions will depend, in part, on the ability of Access to integrate the businesses of MacroChem and Somanta, respectively, with the business of Access. The combination of three independent companies is a complex, costly and time-consuming process. This process may disrupt the business of any or all of the companies, and may not result in the full benefits expected by Access, Macrochem and Somanta.

### We may not successfully commercialize its drug candidates.

Access' 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. Access may be unable to successfully commercialize its' drug candidates because:

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

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

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

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

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



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

Furthermore, its strategy with respect to its 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 its licensing partner. Although Access has had discussions with potential licensing partners with respect to its polymer platinate program, to date Access has not entered into any licensing arrangement. Access may be unable to execute its licensing strategy for polymer platinate.

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

Access has limited experience in the manufacture of pharmaceutical products in clinical quantities or for commercial purposes and Access may not be able to manufacture any new pharmaceutical products that Access may develop. As a result, Access has established, and in the future intends to establish arrangements with contract manufacturers to supply sufficient quantities of products to conduct clinical trials and for the manufacture, packaging, labeling and distribution of finished pharmaceutical products if any of its potential products are approved for commercialization. If Access is unable to contract for a sufficient supply of its potential pharmaceutical products on acceptable terms, its preclinical and human clinical testing schedule may be delayed, resulting in the delay of its clinical programs and submission of product candidates for regulatory approval, which could cause its business to suffer. Its business could suffer if there are delays or difficulties in establishing relationships with manufacturers to produce, package, label and distribute its finished pharmaceutical or other medical products, if any, market introduction and subsequent sales of such products. Moreover, contract manufacturers that Access 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 Access is unable to obtain or retain third party manufacturing on commercially acceptable terms, Access may not be able to commercialize its products as planned. Its potential dependence upon third parties for the manufacture of its products may adversely affect its ability to generate profits or acceptable profit margins and its ability to develop and deliver such products on a timely and competitive basis.

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

# We are subject to extensive governmental regulation which increases its cost of doing business and may affect its ability to commercialize any new products that Access 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 its safety and efficacy. All of its drugs and drug candidates require receipt and maintenance of governmental approvals for commercialization. Preclinical and clinical trials and manufacturing of its drug candidates will be subject to the rigorous testing and approval processes of the FDA and corresponding foreign regulatory authorities. Satisfaction of these requirements typically takes a significant number of years and can vary substantially based upon the type, complexity and novelty of the product. The status of Access' principal products is as follows:

- A mucoadhesive liquid technology product, MuGard<sup>™</sup>, has received marketing approval by the FDA.
- ProLindac<sup>TM</sup> is currently in a Phase 2 trial in Europe.
- ProLindac<sup>™</sup> has been approved for an additional Phase 1 trial in the US by the FDA.
- Thiarabine <sup>TM</sup> is currently in the planning stage for two additional Phase 2 trials in the United States.
- Cobalamin<sup>™</sup> mediated delivery technology is currently in the pre-clinical phase.
- Access also has other products in the preclinical phase.

Due to the time consuming and uncertain nature of the drug candidate development process and the governmental approval process described above, Access cannot assure you when Access, independently or with its collaborative partners, might submit a NDA, for FDA or other regulatory review. Further, our ability to commence and/or complete the above 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 Access' potential drugs for a considerable or indefinite period of time, impose costly procedural requirements upon its 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 Access' marketing as well as its ability to generate significant revenues from commercial sales. Access' 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 Access obtains initial regulatory approvals for its drug candidates, Access' drugs and its manufacturing facilities would be subject to continual review and periodic inspection, and later discovery of previously unknown problems with a drug, manufacture 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 Access can obtain regulatory approvals for the commercial sale of any of its potential drugs, the drug candidates will be subject to extensive preclinical and clinical trials to demonstrate their safety and efficacy in humans. Preclinical or clinical trials of any of its future drug candidates may not demonstrate the safety and efficacy of such drug candidates at all or to the extent necessary to obtain regulatory approvals. In this regard, for example, adverse side effects can occur during the clinical testing of a new drug on humans which may delay ultimate FDA approval or even lead it to terminate its 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 Access' drug candidates could prevent Access from successfully commercializing such candidates and Access could incur substantial additional expenses in its attempts to further develop such candidates and obtain future regulatory approval.

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

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

# We may incur significant liabilities if it fails to comply with stringent environmental regulations or if we do not comply with these regulations in the past.

Access' research and development processes involve the controlled use of hazardous materials. Access is subject to a variety of federal, state and local governmental laws and regulations related to the use, manufacture, storage, handling and disposal of such material and certain waste products. Although Access believes that its activities and its safety procedures for storing, using, handling and disposing of such materials comply with the standards prescribed by such laws and regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such accident, Access could be held liable for any damages that result and any such liability could exceed its 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. Access' competitors in the United States and elsewhere are numerous and include, among others, major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions.

The following products may compete with polymer platinate:

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

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

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

other drug delivery systems.

Companies working on therapies and formulations that may be competitive with Access' 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.

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

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

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

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

In addition, some of Access' competitors have greater experience than Access does in conducting preclinical and clinical trials and obtaining FDA and other regulatory approvals. Accordingly, Access' competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates more rapidly than Access does. 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 Access' research and development efforts or from its joint efforts with collaborative partners therefore may not be commercially competitive with its competitors' existing products or products under development.



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

Access, as a result of its acquisition of MacroChem Corporation and Somanta Pharmaceuticals, Inc., has obtained rights to some product candidates through license agreements with various third party licensors as follows:

- License Agreement, dated as of August 8, 2007, by and between Virium Pharmaceuticals, Inc.(a predecessor in interest to Access) and Southern Research Institute; and
- Exclusive Patent and Know-how Sub-license Agreement between Somanta and Immunodex, Inc. dated August 18, 2005, as amended.

Access is dependent upon these licenses for its rights to develop and commercialize its product candidates. While Access believes it is in compliance with its obligations under the licenses, certain licenses may be terminated or converted to non-exclusive licenses by the licensor if Access breaches the terms of the license. Access cannot guarantee you that the licenses will not be terminated or converted in the future.

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

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

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

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

The drugs that Access is attempting to develop may compete with a number of well-established drugs manufactured and marketed by major pharmaceutical companies. The degree of market acceptance of any drugs developed by it will depend on a number of factors, including the establishment and demonstration of the clinical efficacy and safety of its drug candidates, the potential advantage of its 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 Access may develop independently or with its collaborative partners and if they do not, its 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 United States and the concurrent growth of HMOs and similar organizations that can control or significantly influence the purchase of healthcare services and products; and
- · legislative proposals to reform healthcare or reduce government insurance programs.

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

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

Access' success depends, in part, on its ability to obtain U.S. and foreign patent protection for its drug candidates and processes, preserve its trade secrets and operate its 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. Access cannot assure you that any existing or future patents issued to, or licensed by, it will not subsequently be challenged, infringed upon, invalidated or circumvented by others. As a result, although Access, together with its subsidiaries, are either the owner or licensee to 19 U.S. patents and to 7 U.S. patent applications now pending, and 5 European patents and 13 European patent applications, Access cannot assure you that any additional patents will issue from any of the patent applications owned by, or licensed to, it. Furthermore, any rights that Access may have under issued patents may not provide it with significant protection against competitive products or otherwise be commercially viable.

Access' patents, or the patents of licensors, for the following technologies expire in the years and during the date ranges indicated below:

- · Mucoadhesive technology in 2021,
- · ProLindac<sup>™</sup> in 2021,
- $\cdot$  Thiarabine in 2018,
- · Cobalamin mediated technology between 2009 and 2019

In addition to issued patents, Access has, or has the rights to, a number of pending patent applications. If issued, the patents underlying theses applications could extend the patent life of its technologies beyond the dates listed above.

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



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

Access is highly dependent upon the efforts of its senior management and scientific team, including its President and Chief Executive Officer, Jeffrey B. Davis. The loss of the services of one or more of these individuals could delay or prevent the achievement of its research, development, marketing, or product commercialization objectives. While Access has employment agreements with Jeffrey B. Davis, David P. Nowotnik, PhD its Senior Vice President Research and Development, and Stephen B. Thompson, its Vice President and Chief Financial Officer, their employment may be terminated by them or Access at any time. Mr. Davis', Dr. Nowotnik's and Mr. Thompson's agreements expire within one year and are extendable each year on the anniversary date. As a cost savings measure, we recently lowered the cash compensation of certain of our key employees including our executive officers. Access does not have employment contracts with its other key personnel. Access does not maintain any "key-man" insurance policies on any of its key employees and Access does not intend to obtain such insurance. In addition, due to the specialized scientific nature of its business, Access is highly dependent upon its ability to attract and retain qualified scientific and technical personnel. In view of the stage of its development and its research and development programs, Access has restricted its hiring to research scientists and a small administrative staff and Access has 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 Access' activities, however, and Access may be unsuccessful in attracting and retaining these personnel.

# We may be required to pay liquidated damages to certain investors if it does not maintain an effective registration statement relating to common stock issuable upon conversion of Series A Cumulative Convertible Preferred stock or upon exercise of certain warrants.

Pursuant to issuing Series A Cumulative Convertible Preferred Stock and warrants, Access 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 Access maintain an effective registration statement for common stock issuable upon conversion of Series A Cumulative Convertible Preferred Stock or upon exercise of certain warrants. Access has failed to maintain such an effective registration statement and, as a result, it may be required to pay liquidated damages to certain holders of such Series A Cumulative Convertible Preferred Stock and warrants for the period of time in which an effective registration statement was not in place.

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

Provisions of Access' Certificate of Incorporation, By-laws and Stockholders Rights Plan may make it more difficult for a third party to acquire control of the Company, even if a change in control would benefit Access stockholders. In particular, shares of Access 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 Access' Board of Directors may determine, including, for example, rights to convert into Access common stock. The rights of the holders of Access common stock will be subject to, and may be adversely affected by, the rights of the holders of any of Access' 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 Access. This could limit the price that certain investors might be willing to pay in the future for shares of Access common stock and discourage these investors from acquiring a majority of Access common stock. Further, the existence of these corporate governance provisions could have the effect of entrenching management and making it more difficult to change Access' management.

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

The market price for Access common stock could drop as a result of sales of a large number of its presently outstanding shares or shares that Access may issue or be obligated to issue in the future. Substantially all of the shares of Access common stock that are outstanding as of October \_\_\_\_, 2009, 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 Access to provide reliable financial reports. If Access cannot provide reliable financial reports, Access' operating results could be harmed. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

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

Failure to achieve and maintain an effective internal control environment could cause investors to lose confidence in Access' reported financial information, which could have a material adverse effect on its stock price.

#### **Risks relating to this Offering**

#### We will have immediate and broad discretion over the use of the net proceeds from this offering.

There is no minimum offering amount required as a condition to closing this offering and therefore net proceeds from this offering will be immediately available to us to use at our discretion. We intend to use the net proceeds to further develop our products and product candidates and for working capital and general corporate purposes. 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 13,111,545 shares of common stock outstanding as of October 26, 2009, 13,111,545 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 9,974,531 shares issuable upon conversion of our outstanding preferred stock and 9,835,479 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.

You will incur immediate and substantial dilution as a result of this offering. After giving effect to the sale by us of up to \_\_\_\_\_\_ units offered in this offering at a public offering price of \$\_\_\_\_\_ per unit, and after deducting placement agent commissions and estimated offering expenses payable by us, investors in this offering can expect an immediate dilution of \$\_\_\_\_\_ per share, or \_\_\_%, at the public offering price, assuming no exercise of the warrants. 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 the registration statement covering the shares issuable upon exercise of the warrants contained in the units is no longer effective, the unit warrants will be issued with restrictive legends unless such shares are eligible for sale under Rule 144.



# The offering may not be fully subscribed and, even if the offering is fully subscribed, 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.

The placement agent in this offering will offer the units on a "best-efforts" basis, meaning that we may raise substantially less than the total maximum offering amounts. No refund will be made available to investors if less than all of the units are sold. 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 convertible note outstanding in the principle amount of \$5,500,000 which is due on September 13, 2011 and which we may be unable to repay at maturity.

We have a convertible note outstanding to a high net worth individual in the principle amount of 5.5 million which is due and payable by Access on September 13, 2011. This convertible note accrues interest at the rate of 7.7% paid annually. We may not have the funds to repay the holder of the convertible note at maturity or to continue to pay the interest on the convertible note in the ordinary course 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 common stockholders.

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

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

#### We have outstanding warrants which provide the holders thereof with anti-dilution protection.

The outstanding warrants to purchase shares of Access Common Stock provide the holders of such warrants with anti-dilution protection. Should Access issue additional shares of common stock for a price below \$3.50 per share, the exercise price of the warrants shall be lowered to the lowest issue price below \$3.50 per share which will have the effect of immediately diluting the holders of our Common Stock.

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

Access' 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 its common stock.

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

Additionally, Access' 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 Access' 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 Access' common stock.



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

As calculated by the SEC rules of beneficial ownership, SCO Capital Partners LLC and affiliates, Larry N. Feinberg (Oracle Partners LP, Oracle Institutional Partners LP and Oracle Investment Management Inc.), and Lake End Capital LLC each beneficially owned approximately 57.4%, 11.4% and 7.8%, respectively, of Access' common stock on an as converted basis as of October 26, 2009. Accordingly, they collectively may have the ability to significantly influence or determine the election of all of Access' 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 Access' 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 finds 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**

We estimate that we will receive up to \$\_\_\_\_\_\_ in net proceeds from the sale of units in this offering, based on an assumed price of \$\_\_\_\_\_\_ per unit and after deducting estimated placement agent fees and estimated offering expenses payable by us. 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. 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

If you purchase units in this offering, and assuming no value is attributed to the warrants, your interest will be diluted immediately to the extent of the difference between the assumed public offering price of \$\_\_\_\_ per unit and the as adjusted net tangible book value per share of our common stock immediately following this offering.

Our net tangible book value as of October 26, 2009 was approximately (5.8) million, or approximately (0.50) per share. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of common stock outstanding as of October 26, 2009.

Net tangible book value dilution per unit to new investors represents the difference between the amount per unit paid by purchasers in this offering and the as adjusted net tangible book value per share of common stock immediately after completion of this offering, assuming that no value is attributed to the warrants. After giving effect to our sale of \_\_\_\_\_\_ units in this offering at an assumed public offering price of \$\_\_\_\_\_ per unit, and after deducting the placement agent commissions and estimated offering expenses, our as adjusted net tangible book value as of June 30, 2009 would have been \$\_\_\_\_\_ million, or \$\_\_\_ per share. This represents an immediate increase in net tangible book value of \$\_\_\_\_\_ per unit to purchasers of units in this offering, as illustrated in the following table:

Assumed public offering price per unit Net tangible book value per share as of October, 2009	\$ \$	0
Increase in net tangible book value per unit attributable to new investors Adjusted net tangible book value per share as of June 30, 2009, after	\$	
giving effect to the offering	\$	
Dilution per unit to new investors in the offering	\$	

The above discussion and tables do not include the following:

- 1,832,184 shares of common stock reserved for future issuance under our equity incentive plans. As of October 26, 2009, there were 1,579,904 options outstanding under our equity incentive plans with a weighted average exercise price of \$2.90 per share;
- 9,835,479 shares of common stock issuable upon exercise of outstanding warrants as of October 26, 2009, with exercise prices ranging from \$1.32 per share to \$69.57 per share;
- shares of common stock that will be issued upon exercise of warrants at an exercise price of \$\_\_\_\_\_ per share sold as part of the units in this offering; and
- the conversion of our currently outstanding Convertible Note.

The above discussion and tables assume that our 2,992.3617 shares of Series A Cumulative Convertible Preferred Stock are converted into 9,974,531 shares of common stock at a conversion price of \$3.00 per share.



### PRICE RANGE OF OUR COMMON STOCK

#### **Market Information**

Access' 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 Access' common stock for fiscal years 2009 (year to date), 2008 and 2007. The OTCBB quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

#### **Common Stock**

	Common Stock						
	High		Low				
Fiscal Year 2009 Year-to-date							
First quarter	\$	1.85	\$	0.77			
Second quarter		2.25		1.25			
Third quarter		4.70		1.84			
Fourth quarter (through October 26, 2009)		3.80		2.75			
Fiscal Year Ended December 31, 2008							
First quarter	\$	3.50	\$	1.35			
Second quarter		3.30		1.40			
Third quarter		3.49		2.50			
Fourth quarter		2.75		0.80			
Fiscal Year Ended December 31, 2007							
First quarter	\$	10.66	\$	2.50			
Second quarter		6.75		4.30			
Third quarter		5.16		2.10			
Fourth quarter		4.48		2.10			

### Holders

The number of record holders of Access common stock at October 26, 2009 was approximately 10,900. On October 26, 2009, the closing price for the common stock as quoted on the OTCBB was \$3.30. There were 13,111,545 shares of common stock outstanding at October 26, 2009.

There were 2,992.3617 shares of Series A Cumulative Convertible Preferred Stock convertible into 9,974,531 shares of Common Stock at October 26, 2009.

#### **Options and Warrants**

There are 9,835,479 outstanding warrants and 1,579,904 outstanding options to purchase Access' common equity as of October 26, 2009.

#### **Convertible Notes**

There is \$5.5 million of convertible notes outstanding and convertible into 200,000 shares of common stock as of October 26, 2009.



### **DIVIDEND POLICY**

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

The holders of Series A Cumulative Convertible Preferred Stock are entitled to receive dividends of 6% per annum on their shares Series A Cumulative Convertible Preferred Stock. The dividends are payable by Access semi-annually and may be paid by Access either in cash, or if certain conditions are met, at Access' option, in shares of Access' 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.

### SELECTED CONDENSED CONSOLIDATED FINANCIAL INFORMATION

The following selected condensed consolidated financial information as of and for the years ended December 31, 2008 and 2007, have been derived from our audited financial statements. The financial information as of and for the six months ended June 30, 2009 and 2008 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.

<u>(in thousands, except per share amounts)</u>	For the Six Months Ended June 30,					For the Year Ended December 31,			
		2009	,	2008		2008		2007	
Consolidated Statement of Operations Data:									
Total revenues	\$	104	\$	170	\$	291	\$	57	
Operating loss		(4,051)		(25,126)		(16,915)		(6,900	
Interest and miscellaneous income		16		141		178		125	
Interest and other expense		(262)		(329)		(478)		(3,514	
Loss on extinguishment of debt		-		-		-		(11,628	
Income tax benefit		-		-		-		61	
Loss from continuing operations		(4,297)		(25,314)		(17,215)		(21,856	
Preferred stock dividends		(963)		(2,350)		(3,358)		(14,908	
Discontinued operations, net of taxes of \$61 in 2007		-		-		-		112	
Net loss	\$	(5,260)	\$	(27,664)	\$	(20,573)	\$	(36,652	
Common Stock Data:									
Net loss per basic and diluted common share	\$	(0.48)	\$	(3.45)	\$	(3.51)	\$	(10.32	
Weighted average basic and diluted common shares outstanding		10,954		8,008		5,854		3,552	

	<u>June 30,</u>			Decem				
		2009		2008		2008		2007
<b>Consolidated Balance Sheet Data:</b> Cash, cash equivalents and short term investments	\$	1,231	\$	5,888	\$	2,663	\$	6,921
Total assets		2,351		6,920		4,257		9,149
Deferred revenue		3,789		2,047		2,409		978
Convertible notes		5,500		5,500		5,500		5,564
Total liabilities		16,177		10,994		12,651		8,468
Total stockholders' equity (deficit)		(13,826)		(4,074)		(8,394)		681

### MacroChem Corporation

Below is selected financial information for MacroChem Corporation. We completed our acquisition of MacroChem on February 25, 2009. Historical information from MacroChem's audited financial statements for the fiscal year ended December 31, 2008 is also contained in Access' current report on Form 8-K/A filed with the Securities and Exchange Commission on August 26, 2009. The information is only a summary and should be read in conjunction with MacroChem's financial statements referenced above and accompanying notes.

#### (in thousands, except per share amounts)

CONSOLIDATED STATEMENT OF OPERATIONS DATA:	2008		
Total revenues	\$	4	
Operating loss		(13,812)	
Interest and other income		26	
Interest and other expense		(433)	
Gain on change in value of warrants liability		3,972	
Gain on sale of equipment		7	
Net loss	\$	(10,240)	
Net loss per basic and diluted common share	\$	(0.26)	
Weighted average basic and diluted common shares outstanding		38,934	
CONSOLIDATED BALANCE SHEET DATA:			
	De	cember 31,	
Cash and cash equivalents	\$	14	
Total assets		549	
Current liabilities		3,346	
Total liabilities		3,474	
Stockholders' (deficit) equity	\$	(2,925)	

#### UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

The following unaudited pro forma condensed combined financial statements apply to the merger between MacroChem Corporation ("MacroChem") and Access, by which MacroChem became a wholly owned subsidiary of Access, and are based upon the historical condensed consolidated financial statements and notes thereto (as applicable) of Access and MacroChem. The unaudited pro forma condensed combined balance sheet gives pro forma effect to the merger as if the merger had been completed on December 31, 2008 and combines Access's December 31, 2008 audited consolidated balance sheet with MacroChem's December 31, 2008 audited consolidated balance sheet. The unaudited pro forma condensed combined statement of operations gives pro forma effect to the merger as if it had been completed on January 1, 2008 and combines Access' audited consolidated statement of operations for the year ended December 31, 2008, with MacroChem's audited consolidated statement of operations for the year ended December 31, 2008.

On February 25, 2009, we closed our acquisition of MacroChem through the issuance of an aggregate of approximately 2.5 million shares of our common stock. Prior to our acquisition of MacroChem, SCO, an investment company, held a majority of Access' and MacroChem's voting stock. Specifically, SCO owned 53% of the voting stock of Access and 63% of the voting stock of MacroChem. A non-controlling interest of 37% existed at the merger date of MacroChem. In addition, certain members of SCO's management serve on the board of directors of both Access and MacroChem. Based on these facts, Access and MacroChem were deemed under the common control of SCO. As the entities were deemed under common control, the acquisition was recorded using the pooling-of-interest method and beginning in 2009, the financial information for all periods presented will reflect the financial statements of the combined companies in accordance with Appendix D of Statement of Financial Accounting Standards No. 141R (SFAS 141R), "Business Combinations," for entities under common control.

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

In addition, we issued 125,000 shares of Access common stock valued at \$197,000 to former executives of MacroChem for the settlement of employment agreements.

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

The pro forma adjustments are based upon available information and certain assumptions that Access believes are reasonable under the circumstances.

Total consideration paid in connection with the acquisition included:

- Approximately 2.5 million shares of Access common stock was issued to the common shareholders and the in-the-money warrant holders of MacroChem as consideration having a value of approximately \$3.5 million (the value was calculated using Access' stock price on February 25, 2009 times the shares issued);
- an aggregate of \$106,000 in direct transaction costs; and
- · cancelled receivable from MacroChem of \$635,000.

These unaudited pro forma condensed combined financial statements should be read in conjunction with the historical consolidated financial statements and related notes contained in the annual, quarterly and other reports filed by Access and MacroChem with the Securities and Exchange Commission.

# Pro Forma Condensed Combined Balance Sheet As of December 31, 2008 (Unaudited)

# Historical

		Access	MacroChem	Pro Forma Adjustments		Pro Forma Combined	
ASSETS							
Current assets							
Cash and cash equivalents	\$	2,663,000	\$ 14,000			\$ 2,677,0	
Receivables		147,000	-	((25.000)	(0)	147,0	)00
Receivables due from MacroChem		635,000	-	(635,000)	(f)	175.0	-
Prepaid expenses and other current expenses		105,000	70,000			175,0	
Total current assets		3,550,000	84,000			2,999,0	)00
Property and equipment, net		87,000	8,000			95,0	
Patents net		542,000	457,000			999,0	)00
Other assets		78,000				78,0	
Total assets	\$	4,257,000	\$ 549,000			\$ 4,171,0	)00
LIABILITIES AND STOCKHOLDERS' DEFICIT							
Current liabilities							
Accounts payable	\$	1,970,000	\$ 1,317,000	106,000	(e)	\$ 3,393,0	000
Accrued expenses		748,000	547,000			1,295,0	)00
Dividends payable		1,896,000	-			1,896,0	000
Accrued interest payable		128,000	17,000	(17,000)	(b)	128,0	)00
Current portion of deferred revenue		164,000	5,000	(5,000)	(d)	164,0	)00
Notes payable		-	825,000	(825,000)	(b)		-
Payables due Access			635,000	(635,000)	(f)		-
Total current liabilities		4,906,000	3,346,000			6,876,0	)00
Long-term deferred revenue		2,245,000	24,000	(24,000)	(d)	2,245,0	000
Warrants liability		-	104,000	(104,000)	(d)		-
Long-term debt		5,500,000				5,500,0	)00
Total liabilities		12,651,000	3,474,000			14,621,0	)00
Stockholders' equity (deficit)							
Preferred stock		-	-				-
Common stock		70,000	459,000	25,000	(a)	104,0	)00
				$8,000 \\ 1.000$	(b) (c)		
				(459,000)	(c) (d)		
Additional paid-in capital		127,482,000	97,763,000	508,000	(a)	226,783,0	000
				834,000	(b)		
				196,000	(c)		
Notes receivable from stockholders		(1,045,000)				(1,045,0	
Treasury stock, at cost		(4,000)			(d)	(4,0	
Accumulated deficit		(134,897,000)	(101,088,000)	(197,000) (106,000)	(c) (e)	(236,288,0	)00)
Total stockholders' equity (deficit)	_	(8,394,000)	(2,925,000)	(100,000)		(10,450,0	
Total liabilities and stockholders' equity (deficit)	\$	4,257,000	\$ 549,000			\$ 4,171,0	)00
	_						-

See accompanying Notes to Pro Forma Condensed Combined Balance Sheet

### Notes to Pro Forma Condensed Combined Balance Sheet

- Note 1: The above statement gives effect to the following pro forma adjustments necessary to reflect the merger of Access and MacroChem, entities deemed under common control, as if the transaction had occurred on December 31, 2008.
  - a) To record the exchange, for accounting purposes, by MacroChem shareholders of their common stock and in-the-money warrants for 2,500,000 shares of Access and the impact of pro-forma adjustments to additional paid-in capital in the amount of \$508,000.
  - b) To record Access common stock exchanged for notes payable of \$825,000 and accrued interest of \$17,000.
  - c) To record Access common stock issued to former executives of MacroChem for the settlement of employment agreements.
  - d) To eliminate the common stock, treasury stock, warrant liabilities and deferred revenue of MacroChem.
  - e) To record \$106,000 in merger costs.
  - f) To eliminate intercompany notes payable/receivable of \$635,000.

After the consummation of the transactions described herein, Access had 100,000,000 common shares authorized, approximately 10,434,474 common shares issued and outstanding, 2,000,000 preferred shares authorized with approximately 3,242.8617 shares of Series A Cumulative Convertible Preferred Stock issued and outstanding, convertible into 10,809,539 shares of Access common stock.

#### Pro Forma Condensed Combined Statement of Operations For the Twelve Months Ended December 31, 2008 (Unaudited)

Historical

		Access	Ν	/lacroChem		Pro Forma Combined
Revenues	\$	291,000	\$	4,000	\$	295,000
Expenses						
Research and development		12,613,000		10,622,000		23,235,000
General and administrative		4,340,000		3,123,000		7,463,000
Depreciation and amortization		253,000		71,000		324,000
Total expenses		17,206,000		13,816,000		31,022,000
Loss from operations		(16,915,000)		(13,812,000)		(30,727,000)
Interest and other income		178,000		33,000		211,000
Interest and other expenses		(478,000)		(433,000)		(911,000)
Change in fair value of warrants liability		-		3,972,000		3,972,000
		(300,000)		3,572,000		3,272,000
Net loss		(17,215,000)		(10,240,000)		(27,455,000)
Less preferred stock dividends		(3,358,000)		-		(3,358,000)
Net loss allocable to common stockholders	\$	(20,573,000)	\$	(10,240,000)	\$	(30,813,000)
Basic and diluted loss per common share Loss from operations allocable to all common stockholders	\$	(3.51)	\$	(0.26)	\$	(3.31)
Weighted average basic and diluted common shares outstanding	_	5,854,031		38,934,207	_	9,321,031

Notes to Pro Forma Condensed Combined Statement of Operations

Note 1: The above statement gives effect to the merger of Access and MacroChem, as if the merger had occurred on January 1, 2008.

Note 2: The pro forma combined-weighted average number of common shares outstanding shares is based on the weighted average number of shares of common stock of Access during the period plus those shares to be issued in conjunction with the merger. A reconciliation between Access' historical weighted average shares outstanding and pro forma weighted average shares outstanding is as follows:

Historical	5,854,031
MacroChem equivalent shares giving effect to the merger	2,500,000
Shares issued to former MacroChem executives	125,000
Shares issued for notes payable and interest	842,000
Total	9,321,031

#### 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. is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one approved product, two products in Phase 2 of clinical development and several products in pre-clinical development. Low priority clinical and pre-clinical programs will be dependent on our ability to enter into collaborative arrangements. Our description of our business, including our list of products and patents, takes into consideration our acquisition of MacroChem Corporation which closed February 25, 2009.

- MuGard<sup>™</sup> is our approved product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the Food & Drug Administration ("FDA"). MuGard has been launched in Germany, Italy, UK, Greece and the Nordic countries by our European commercial partner, SpePharm.
- Our lead development candidate for the treatment of cancer is ProLindac<sup>™</sup>, a nanopolymer DACH-platinum prodrug. We recently completed a Phase 2 clinical trial on ProLindac in the EU in patients with ovarian cancer. The clinical study had positive safety and efficacy results. We are currently planning a number of combination trials, looking at combining ProLindac with other cancer agents such as taxol and gemcitabine, in solid tumor indications including colorectal and ovarian. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has sales in excess of \$2.0 billion.
- Thiarabine, or 4-thio Ara-C, is a next generation nucleoside analog licensed from Southern Research Institute. Previously named SR9025 and OSI-7836, the compound has been in two Phase 1/2 solid tumor human clinical trials and was shown to have anti-tumor activity. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and intend to initiate additional Phase 2 clinical trials in adult AML, ALL and other indications.
- Cobalamin<sup>™</sup> is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We are currently developing a product for the oral delivery of insulin, and are conducting sponsored development of a product for oral delivery of human growth hormone.
- Cobalamin-mediated cancer targeted delivery is a preclinical technology which makes use of the fact that cell surface receptors for vitamins such as B12 are often overexpressed by cancer cells.



#### **Access Drug Portfolio**

Compound	Originator	Technology	Indication	Clinical Stage (1)
MuGard™	Access	Mucoadhesive liquid	Mucositis	(510k) Marketing clearance received
ProLindacTM (Polymer Platinate, AP5346)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Thiarabine (4-thio Ara-C)	Southern Research Institute	Small molecule	Cancer	Phase 1/2
Oral Insulin	Access	Cobalamin	Diabetes	Pre-clinical
Oral Delivery System	Access	Cobalamin	Various	Pre-clinical
Cobalamin-Targeted Therapeutics	Access	Cobalamin	Anti-tumor	Pre-clinical

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

(2) Licensed from the School of Pharmacy, The University of London.

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

#### **RECENT EVENTS**

On October 6, 2009, we announced that we signed an agreement with iMedicor for the North American launch of MuGard. iMedicor's highly targeted Alerts System application will begin introducing MuGard by the end of the year to the 216,000 selected physicians in the Unites States.

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

On August 3, 2009, we announced that we commenced a new clinical study of ProLindac in France. The study will examine dose levels and regimens of ProLindac monotherapy in cancer patients, provide additional data to support design of combinations studies, and extend the safety database. Two ovarian cancer patients have been enrolled in the study to date, and it is anticipated 6 to 12 patients will be enrolled this year in advance of enrolling patients in trial evaluating ProLindac in combination with other chemotherapies.

On July 29, 2009, we announced that we are evaluating strategic options for the commercialization of MuGard in North America. Frank Jacobucci, formerly President & CEO of Milestone Biosciences, has joined Access as a consultant, and will assist with ongoing reimbursement, manufacturing and commercial launch activities at Access, while discussions with potential licensee and co-promotion partners is ongoing.

On July 23, 2009, we announced that our European partner, SpePharm, is collecting data from a post approval study of MuGard in head and neck cancer patients undergoing radiation treatment in the UK showing prevention of oral mucositis. In a multi-center study expected to enroll a total of 280 patients, patients are provided with seven weeks of MuGard therapy, and begin using MuGard one week prior to radiation treatment and then throughout the subsequent six weeks of planned therapy. The first 140 patients being treated in this assessment study have been enrolled and treated, and as of the time of the update, none of these patients have experienced any oral mucositis.

On July 7, 2009, we announced new preclinical data demonstrating that thiarabine shows remarkable efficacy in the prevention and treatment of rheumatoid arthritis (RA). In a well-established animal model for RA, an exceptional restoration of joint structure was observed in the studies, which were conducted at Wayne State University School of Medicine and at Southern Research Institute.

On June 17, 2009, we announced that we signed evaluation agreements with two biopharmaceutical companies for our Cobalamin<sup>™</sup> Oral Drug Delivery Technology. Under the terms of the agreements, both companies plan to evaluate Access' oral insulin product in preclinical models as a prerequisite to entering licensing discussions.

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

### **RESULTS OF OPERATIONS**

#### Comparison of Second Quarter 2009 with the Second Quarter of 2008

On February 25, 2009, we closed our acquisition of MacroChem Corporation through the issuance of an aggregate of approximately 2.5 million shares of our common stock. Prior to our acquisition of MacroChem, SCO, an investment company, held a majority of Access' and MacroChem's voting stock. Specifically, SCO owned 53% of the voting stock of Access and 63% of the voting stock of MacroChem. A non-controlling interest of 37% existed at the merger date of MacroChem. In addition, certain members of SCO's management serve on the board of directors of both Access and MacroChem. Based on these facts, Access and MacroChem were deemed under the common control of SCO. As the entities were deemed under common control, the acquisition was recorded using the pooling-of-interest method and the financial information for all periods presented reflects the financial statements of the combined companies in accordance with Appendix D of Statement of Financial Accounting Standards No. 141R (SFAS 141R), "Business Combinations," for entities under common control.

Our licensing revenue for the second quarter of 2009 was \$63,000 as compared to \$22,000 for 2008, an increase of \$41,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We had sponsored research and development income of \$110,000 in 2008. The research and development agreement was completed in 2008.

Total research and development spending for the second quarter of 2009 was \$582,000, as compared to \$10,855,000 for 2008, a decrease of \$10,273,000. The decrease in expenses was primarily due to:

•	research and development expenses incurred by MacroChem in the second quarter of 2008, which are no longer ongoing,
	and MacroChem's acquisition of Virium on April 18, 2008, which resulted in a second quarter non-cash in-process
	research and development expense (\$9,657,000);
	lower costs for product manufacturing for a new ProLindac clinical trial in 2009 as some manufacturing is complete and
	a clinical trial has started (\$459,000);
•	lower salary and related expenses (\$67,000);
•	lower scientific consulting expenses (\$63,000);
•	offset by higher expenses due to the cost of option grants (\$72,000); and
•	other net decreases in research spending (\$99,000).

Total general and administrative expenses were \$1,507,000 for the second quarter of 2009, a decrease of \$772,000 compared to 2008 expenses of \$2,279,000 for the same quarter. The decrease in expenses was due primarily to the following:

•	general and administrative expenses incurred by MacroChem in the second quarter of 2008 that are no longer ongoing
	(\$1,177,000);
•	lower patent expenses (\$172,000);
•	lower salary and related expenses (\$17,000);
•	offset by higher business professional expenses (\$214,000);
•	higher shareholder consultant expenses (\$185,000);
•	higher expenses due to the cost of option grants (\$96,000);
•	accrual of potential liquidated damages under an investor rights agreement with certain investors (\$109,000); and
	other net decreases in general and administrative expenses (\$10,000).

Depreciation and amortization was \$66,000 for the second quarter of 2009, as compared to \$78,000 for 2008, a decrease of \$12,000. The decrease in expenses was primarily due to assets becoming fully depreciated.

Total operating expenses for the second quarter of 2009, were \$2,155,000 as compared to total operating expenses of \$13,212,000 for same period in 2008, a decrease of \$11,057,000 for the reasons listed above.

Interest and miscellaneous income was \$2,000 for the second quarter of 2009, as compared to \$40,000 for the same period in 2008, a decrease of \$38,000. The decrease in interest and miscellaneous income was due to lower average cash balances during 2009 versus 2008.

Interest and other expense was \$118,000 for the second quarter of 2009, as compared to \$221,000 in 2008, a decrease of \$103,000. The decrease in interest and other expense was due to MacroChem notes payable that were exchanged and cancelled for shares of our common stock in connection with our acquisition of MacroChem. The notes payable were issued in the second quarter of 2008.

Preferred stock dividends of \$483,000 were accrued for the second quarter of 2009 and \$517,000 for 2008, a decrease of \$34,000. The decrease is due to preferred shareholders converting their ownership to common stock. Dividends are paid semi-annually in either cash or common stock.

Net loss allocable to common stockholders for the second quarter of 2009, was \$2,691,000, or a \$0.24 basic and diluted loss per common share, compared with a loss of \$13,778,000, or a \$1.69 basic and diluted loss per common share for the same period in 2008, a decreased loss of \$11,087,000.

# Comparison of Six-Months ended June 30, 2009 with Six-Months ended June 30, 2008

On February 25, 2009, we closed our acquisition of MacroChem Corporation through the issuance of an aggregate of approximately 2.5 million shares of our common stock. Prior to our acquisition of MacroChem, SCO, an investment company, held a majority of Access' and MacroChem's voting stock. Specifically, SCO owned 53% of the voting stock of Access and 63% of the voting stock of MacroChem. A non-controlling interest of 37% existed at the merger date of MacroChem. In addition, certain members of SCO's management serve on the board of directors of both Access and MacroChem. Based on these facts, Access and MacroChem were deemed under the common control of SCO. As the entities were deemed under common control, the acquisition was recorded using the pooling-of-interest method and the financial information for all periods presented reflects the financial statements of the combined companies in accordance with Appendix D of Statement of Financial Accounting Standards No. 141R (SFAS 141R), "Business Combinations," for entities under common control.

Our licensing revenue for the first six months of 2009 was \$104,000 as compared to \$39,000 for the same period of 2008. We recognize licensing revenue over the period of the performance obligation under our licensing agreement. We have received upfront licensing payments from SpePharm Holding, B.V., RHEI, JCOM and ASK.

We had sponsored research and development income of \$131,000 in 2008. The research and development agreement was completed in 2008.

Total research and development spending for the first six months of 2009 was \$1,269,000, as compared to \$21,012,000 for the same period in 2008, a decrease of \$19,743,000. The decrease in expenses was primarily due to:

	the Somanta acquisition resulted in a one-time non-cash in-process research and development expense in the first quarter of 2008 (\$8,879,000);
	research and development expenses incurred by MacroChem in the first six months of 2008, which are no longer ongoing (\$465,000);
	MacroChem's acquisition of Virium on April 18, 2008 which resulted in a one-time non-cash in-process research and development expense (\$9,657,000);
•	lower costs for product manufacturing due to the start of a new ProLindac clinical trial (\$594,000);
•	lower salary and related expenses (\$60,000);
	lower scientific consulting expenses (\$60,000);
	lower travel expenses (\$56,000);
	offset by higher expenses due to option grants (\$95,000); and
•	other net decreases in research spending (\$67,000).

Total general and administrative expenses were \$2,754,000 for the first six months of 2009, a decrease of \$1,364,000 over 2008 expenses of \$4,118,000. The decrease in spending was due primarily to the following:

	general and administrative expenses incurred by MacroChem in the first six months of 2008 that are no longer ongoing (\$1,996,000);
•	lower salary and related expenses (\$38,000);
•	offset by higher business professional expenses (\$302,000);
•	accrual of potential liquidated damages under an investor rights agreement with certain investors (\$267,000);
	higher shareholder consultant expenses (\$153,000);
•	higher expenses due to the cost of option grants (\$73,000); and
•	other net decreases in general and administrative expenses (\$125,000).

Depreciation and amortization was \$132,000 for the first six months of 2009 as compared to \$166,000 for the same period in 2008 reflecting a decrease of \$34,000. The decrease in depreciation and amortization was due to assets becoming fully depreciated.

Total operating expenses for the first six months of 2009 were \$4,155,000 as compared to total operating expenses of \$25,296,000 for same period in 2008, a decrease of \$21,141,000 for the reasons listed above.

Interest and miscellaneous income was \$16,000 for the first six months of 2009 as compared to \$141,000 for the same period of 2008, a decrease of \$125,000. The decrease in interest and miscellaneous income was due to lower average cash balances during 2009 versus 2008.

Interest and other expense was \$262,000 for the first six months of 2009 as compared to \$329,000 in 2008, a decrease of \$67,000. The decrease in interest and other expense was due to MacroChem notes payable that were exchanged and cancelled for shares of our common stock in connection with our acquisition of MacroChem. The notes payable were issued in the second quarter of 2008.

Preferred stock dividends of \$963,000 were accrued for the first six months of 2009 and \$1,042,000 for 2008, a decrease of \$79,000. The decrease is due to preferred shareholders converting their ownership to common stock offset by a placement of preferred stock that closed in February 4, 2008. Dividends are paid semi-annually in either cash or common stock.

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

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

Net loss allocable to common stockholders for the first six months of 2009 was \$5,260,000, or a \$0.48 basic and diluted loss per common share, compared with a loss of \$27,664,000, or a \$3.45 basic and diluted loss per common share for the same period in 2008, a decreased loss of \$22,404,000.

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

# LIQUIDITY AND CAPITAL RESOURCES

We have funded our operations primarily through private sales of common stock, preferred stock, convertible notes and through licensing agreements. Our principal source of liquidity is cash and cash equivalents. Licensing fees provided some funding for operations during the quarter ended June 30, 2009. As of June 30, 2009, our cash and cash equivalents were \$1,231,000 and our net cash burn rate for the six months ended June 30, 2009, was approximately \$241,000 per month. As of June 30, 2009, our working capital deficit was \$5,842,000. Our working capital deficit at June 30, 2009 represented an increase of \$1,187,000 as compared to our working capital deficit as of December 31, 2008 of \$4,655,000. The increase in the working capital deficit at June 30, 2009 reflects milestone payments from our licensing agreements offset by operating expenses which included manufacturing product scale-up for our new ProLindac trial and MacroChem expenses. As of June 30, 2009, we had one convertible note outstanding in the principle amount of \$5.5 million which is due September 13, 2011.

After the second quarter of 2009 closed, we received \$1,000,000 in license receipts from an existing license agreement. Our cash balance at August 12, 2009 was \$1,553,000.

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

We have generally incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of June 30, 2009 of \$241,226,000. We expect that our capital resources will be adequate to fund our current level of operations into the first quarter of 2010. However, our ability to fund operations over this time could change significantly depending upon changes to future operational funding obligations or capital expenditures. As a result we may be required to seek additional financing sources within the next twelve months. We cannot assure you that we will ever be able to generate significant product revenue or achieve or sustain profitability.

In order to conserve cash for the operations of Access, management, employees and consultants reduced their monthly stipends. Some consultants also agreed to take common stock and warrants for their services.

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.

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

Currently, one noteholder holding \$5.5 million worth of 7.7% convertible notes has amended their note to a new maturity date, September 13, 2011.

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

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

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

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

# Asset Impairment

Our intangible assets at December 31, 2007 consist primarily of patents acquired in acquisitions and licenses which were recorded at fair value on the acquisition date. We perform an impairment test on at least an annual basis or when indications of impairment exist. At December 31, 2007, Management believes no impairment of our intangible assets exists.

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

# Revenues

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



#### Stock Based Compensation Expense

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

We adopted SFAS 123(R) using the modified prospective transition method, which requires the application of the accounting standard as of January 1, 2006, the first day of the Company's 2006 fiscal year. Our consolidated financial statements for the years ended December 31, 2007 and 2006, reflect the impact of SFAS 123(R). In accordance with the modified prospective transition method, our consolidated financial statements for prior periods have not been restated to include the impact of SFAS 123(R). Stock-based compensation expense recognized under SFAS 123(R) for the years ended December 31, 2007 and 2006 was approximately \$1,048,000 and \$284,000, respectively.

SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service period in the company's Statement of Operations. Prior to the adoption of SFAS 123(R), we accounted for stock-based awards to employees and directors using the intrinsic value method in accordance with APB No. 25 as allowed under SFAS No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"). Under the intrinsic value method, no stock-based compensation expense for stock option grants was recognized because the exercise price of our stock options granted to employees and directors equaled the fair market value of the underlying stock at the date of grant. There were no restricted stock awards granted in either 2006 or 2007 ...

Stock-based compensation expense recognized in the our Statement of Operations for the years ended December 31, 2007 and 2006 includes compensation expense for share-based payment awards granted prior to, but not yet vested as of December 31, 2005, based on the grant date fair value estimated in accordance with the pro forma provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS 123 and compensation expense for the share-based payment awards granted subsequent to December 31, 2005, based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). Stock-based compensation expense recognized in the Company's Statement of Operations for the year ended December 31, 2007 and 2006 is based on awards ultimately expected to vest and has been reduced for estimated forfeitures, which currently is nil. SFAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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

#### Accounting for Uncertain Tax Positions

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



#### **Recent Accounting Pronouncements**

In June 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109, Accounting for Income Taxes ("FIN 48"), to create a single model to address accounting for uncertainty in tax positions. FIN 48 clarifies the accounting for income taxes by prescribing a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. FIN 48 also provides guidance on derecognition, measurement, classification, interest, and penalties, accounting in interim periods, disclosure and transition. The Company adopted FIN 48 as of January 1, 2007, and the adoption did not have a material impact on the Company's consolidated financial statements or effective tax rate and did not result in any unrecognized tax benefits.

Interest costs and penalties related to income taxes are classified as interest expense and general and administrative costs, respectively, in the Company's consolidated financial statements. For the years ended December 31, 2007 and 2006, the Company 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. The Company is currently subject to a three year statute of limitations by major tax jurisdictions. The Company and its subsidiaries file income tax returns in the U.S. federal jurisdiction.

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

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

# **Off-Balance Sheet Transactions**

#### **DESCRIPTION OF BUSINESS**

### Business

Access Pharmaceuticals, Inc. (together with our subsidiaries, "We", "Access" or the "Company") is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one approved product, two products at Phase 2 of clinical development and several products in pre-clinical development. Low priority clinical and pre-clinical programs will be dependent on our ability to enter into collaborative arrangements. Certain of our development programs are dependent upon our ability to secure approved funding for such projects. Our description of our business, including our list of products and patents, takes into consideration our acquisition of MacroChem Corporation which closed February 25, 2009 and Somanta Pharmaceuticals, Inc. which closed on January 4, 2008.

- MuGard<sup>™</sup> is our approved product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the Food & Drug Administration ("FDA"). MuGard has been launched in Germany, Italy, UK, Greece and the Nordic countries by our European commercial partner, SpePharm.
- Our lead development candidate for the treatment of cancer is ProLindac<sup>™</sup>, a nanopolymer DACH-platinum prodrug. We recently completed a Phase 2 clinical trial on ProLindac in the EU in patients with ovarian cancer. The clinical study had positive safety and efficacy results. We are currently planning a number of combination trials, looking at combining ProLindac with other cancer agents such as taxol and gemcitabine, in solid tumor indications including colorectal and ovarian. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has sales in excess of \$2.0 billion.
- Thiarabine, or 4-thio Ara-C, is a next generation nucleoside analog licensed from Southern Research Institute. Previously named SR9025 and OSI-7836, the compound has been in two Phase 1/2 solid tumor human clinical trials and was shown to have antitumor activity. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and intend to initiate additional Phase 2 clinical trials in adult AML, ALL and other indications.
- Cobalamin<sup>™</sup> is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We are currently developing a product for the oral delivery of insulin, and are conducting sponsored development of a product for oral delivery of human growth hormone.
- Cobalamin-mediated cancer targeted delivery is a preclinical technology which makes use of the fact that cell surface receptors for vitamins such as B12 are often overexpressed by cancer cells.

# **Access Drug Portfolio**

Compound	Originator	Technology	Indication	Clinical Stage (1)
MuGard™	Access	Mucoadhesive liquid	Mucositis	(510k) Marketing clearance received
ProLindacTM (Polymer Platinate, AP5346)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Thiarabine (4-thio Ara- C)	Southern Research Institute	Small molecule	Cancer	Phase 1/2
Oral Insulin	Access	Cobalamin	Diabetes	Pre-clinical
Oral Delivery System	Access	Cobalamin	Various	Pre-clinical
Cobalamin-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>TM</sup> - Mucoadhesive Liquid Technology (MLT)

Mucositis is a debilitating condition involving extensive inflammation of mouth tissue that affects annually an estimated 400,000 cancer patients in the United States undergoing chemotherapy and radiation treatment. 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 worldwide.

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

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

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

These data confirmed the fact that MuGard could represent an important advancement in the management and prevention of mucositis. On December 13, 2006, we announced that we had received marketing clearance for MuGard from FDA for the indication of the management of oral wounds including mucositis, aphthous ulcers and traumatic ulcers.



In August 2007, we signed a definitive licensing agreement with SpePharm Holding, B.V. under which SpePharm will market MuGard in Europe. MuGard sales started in Europe in the second quarter of 2009. In January 2008, we signed a definitive licensing agreement with RHEI Pharmaceuticals, Inc. under which RHEI will market MuGard in China and other Southeast Asian countries.

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. Also on July 29, 2009, we announced that Mr. Frank Jacobucci, formerly President & CEO of Milestone Biosciences, has joined Access as a consultant, and will assist with ongoing reimbursement, manufacturing and commercial launch activities at Access, while discussions with potential licensee and co-promotion partners is ongoing.

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

# **Products in Development**

# ProLindac<sup>™</sup> (Polymer Platinate, AP5346) DACH Platinum

Chemotherapy, surgery and radiation are the major components in the clinical management of cancer patients. Chemotherapy serves as the primary therapy for some solid tumors and metastases and is increasingly used as an adjunct to radiation and surgery to improve their effectiveness. For chemotherapeutic agents to be effective in treating cancer patients, however, the agent must reach the target cells in effective quantities with minimal toxicity in normal tissues.

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

Oxaliplatin, a compound of DACH platinum, is a chemotherapeutic which was initially approved in Europe in 1999 for the treatment of colorectal cancer. It is now also being marketed worldwide and generated sales in excess of \$2 billion in 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-flurouracil and folinic acid (known as the FOLFOX regime) is indicated for the first-line treatment of metastatic colorectal cancer in Europe and the U.S. The colorectal cancer market is a significant opportunity as there are over 940,000 reported new cases annually worldwide, increasing at a rate of approximately three percent per year, and 500,000 deaths.

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

Utilizing a biocompatible water-soluble polymer (HPMA) as a drug carrier, Access' drug candidate ProLindac, links DACH platinum to a polymer in a manner which permits the selective release of active drug to the tumor by several mechanisms. The main release mechanism takes advantage of the differential pH in tumor tissue compared to healthy tissue. The polymer also capitalizes on the biological differences in the permeability of blood vessels at tumor sites versus normal tissue. In this way, tumor selective delivery and platinum release is achieved. The ability of ProLindac to inhibit tumor growth has been evaluated in more than ten preclinical models. Compared with the marketed product oxaliplatin, ProLindac was superior, and in several cases markedly superior in most of these models. Preclinical studies of the delivery of platinum to tumors in an animal model have shown that, compared with oxaliplatin at equitoxic doses, ProLindac delivers in excess of 16 times more platinum to the tumor. An analysis of tumor DNA, which is the main target for anti-cancer platinum agents, has shown that ProLindac delivers approximately 14 times more platinum to tumor DNA than oxaliplatin. Results from preclinical efficacy studies conducted in the B16 and other tumor models have also shown that ProLindac is superior to oxaliplatin in inhibiting the growth of tumors. An extensive preclinical package has been developed supporting the development of ProLindac.

In 2005, we completed a Phase 1 multi-center clinical study conducted in Europe, which enrolled 26 patients. The study was reported in a journal publication, Cancer Chemotherapy and Pharmacology, 60(4): 523-533 in 2007. The European trial was designed to identify the maximum tolerated dose, dose limiting toxicities, the pharmacokinetics of the platinum in plasma and the possible anti-tumor activity of ProLindac. The open-label, non-randomized, dose-escalation Phase 1 study was performed at two European centers. ProLindac was administered as an intravenous infusion over one hour, once a week on days 1, 8 and 15 of each 28-day cycle to patients with solid progressive tumors. We obtained results in 26 patients with a broad cross-section of tumor types, with doses ranging from 80-1,280 mg Pt/m<sup>2</sup>.

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

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

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

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

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

On August 3, 2009, we announced that we commenced a new clinical study of ProLindac in France. The study will examine dose levels and regimens of ProLindac monotherapy in cancer patients, provide additional data to support design of combinations studies, and extend the safety database. Two ovarian cancer patients have been enrolled in the study to date, and it is anticipated 6 to 12 patients will be enrolled this year in advance of enrolling patients in trial evaluating ProLindac in combination with other chemotherapies.

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

## Thiarabine (4-thio Ara-C)

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

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

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

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

In the first phase 1 study, 26 patients with incurable advanced and/or metastatic solid tumors were enrolled. The protocol involved dose escalation, starting at 100 mg/m2 iv over 30 minutes on days 1 and 8, every three weeks. Patients were dosed at 200, 400, 500, and 600 mg/m2.

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/m2. Unlike previous observations with gemcitabine and ara-C (where the DLT is myelosupression; leucopenia and thrombocytopenia), there were no grade four toxicities and no hematological toxicities other than reversible, lymphopenia. Investigators concluded that the (Grade 3) dose-limiting toxicities were fatigue, rash, fever, seizure and lymphopenia.

A second solid tumor phase 1 trial was carried out to explore other schedules. The schedules were 200 mg/m2 via 60-minute IV infusion every 21 days, 5-minute bolus on same schedule, and 5-minute bolus weekly for 4 weeks starting with a dose of 100 mg/m2. Of the 27 evaluable patients, 7 patients (bladder cancer and mesothelioma) achieved disease stabilization (median 3.7 months, range 1.9-5.4). The main toxicity was fatigue, which appeared to be schedule independent.

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. Access plans to initiate further thiarabine clinical studies in at least one of these patient populations subject to funding or partnering.

## **Drug Development Strategy**

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

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

Our strategy is to focus on our polymer therapeutic program for the treatment of cancer while continuing to develop technologies such as Cobalamin-mediated oral drug delivery and Cobalamin-mediated tumor targeting which could provide us with a revenue stream in the short term through commercialization or outlicensing to fund our longer-term polymer and oncology drug development programs such as Thiarabine. To reduce financial risk and financing requirements, we are directing our resources to the preclinical and early clinical phases of development. Where the size of the necessary clinical studies and cost associated with the later clinical development phases are significant, we plan to co-develop with or to outlicense to marketing partners our therapeutic product candidates. By forming strategic alliances with pharmaceutical and/or biotech companies, we believe that our technology can be more rapidly developed and successfully introduced into the marketplace.

We will continue to evaluate the most cost-effective methods to advance our programs. We 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 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 for IND submission. External investigators and scaleup manufacturing facilities are selected in conjunction with our consultants. The initial Phase 1 and Phase 2 studies are conducted by institutions and investigators supervised and monitored by our employees and contract research organizations. We do not plan to have an extensive clinical development organization as we plan to have the advance phases of this process conducted by a development partner. Should we conduct Phase 3 clinical studies we expect to engage a contract research organization to perform this work.

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

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

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

## Scientific Background

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

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

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

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

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

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



Each of these platforms is discussed below:

# Synthetic Polymer Targeted Drug Delivery Technology

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

#### Cobalamin<sup>™</sup>-Mediated Oral Delivery Technology

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

The difficulty in administering proteins orally is their susceptibility to degradation by digestive enzymes, their inability to cross the intestinal wall and their rapid excretion by the body. Over the years, many different methodologies for making protein drugs available orally have been attempted. Most of the oral protein delivery technologies involve protecting the protein degradation in the intestine. More recently, strategies have been developed that involve coadministering the protein or peptide with permeation enhancers, which assist in passive transit through the gut wall or by attaching the protein or peptide to a molecule that transports the protein across the gut wall. However, the field of oral drug delivery of proteins and peptides has yet to achieve successful commercialization of a product (although positive results have been achieved in early clinical trials for some products under development).

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

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



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

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

# Cobalamin<sup>TM</sup>-Mediated Targeted Delivery Technology

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

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

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

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

- passive tumor targeting involves transporting anti-cancer agents through the bloodstream to tumor cells using a "carrier" molecule. Many different carrier molecules, which can take a variety of forms (micelles, nanoparticles, liposomes and polymers), are being investigated as each provides advantages such as specificity and protection of the anti-cancer drug from degradation due to their structure, size (molecular weights) and particular interactions with tumor cells. Our polymer platinate program is a passive tumor targeting technology.
- active tumor targeting involves attaching an additional fragment to the anticancer drug and the carrier molecule to create a new "targeted" agent that will actively seek a complementary surface receptor to which it binds (preferentially located on the exterior of the tumor cells). The theory is that the targeting of the anti-cancer agent through active means to the affected cells should allow more of the anti-cancer drug to enter the tumor cell, thus amplifying the response to the treatment and reducing the toxic effect on bystander, normal tissue.

Examples of active targeting fragments include antibodies, growth factors and vitamins. Our scientists have specifically focused on using Cobalamin compounds (analogs of vitamin B12), but we have also used and have certain intellectual property protection for the use of folate and biotin which may more effectively target anti-cancer drugs to certain solid tumors.

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

#### **Other Key Developments**

On October 6, 2009, we announced that we signed an agreement with iMedicor for the North American launch of MuGard. iMedicor's highly targeted Alerts System application will begin introducing MuGard by the end of the year to the 216,000 selected physicians in the Unites States.

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

On August 3, 2009, we announced that we commenced a new clinical study of ProLindac in France. The study will examine dose levels and regimens of ProLindac monotherapy in cancer patients, provide additional data to support design of combinations studies, and extend the safety database. Two ovarian cancer patients have been enrolled in the study to date, and it is anticipated 6 to 12 patients will be enrolled this year in advance of enrolling patients in trial evaluating ProLindac in combination with other chemotherapies.

On July 29, 2009, we announced that we are evaluating strategic options for the commercialization of MuGard in North America. Frank Jacobucci, formerly President & CEO of Milestone Biosciences, has joined Access as a consultant, and will assist with ongoing reimbursement, manufacturing and commercial launch activities at Access, while discussions with potential licensee and co-promotion partners is ongoing.

On July 23, 2009, we announced that our European partner, SpePharm, is collecting data from a post approval study of MuGard in head and neck cancer patients undergoing radiation treatment in the UK showing prevention of oral mucositis. In a multi-center study expected to enroll a total of 280 patients, patients are provided with seven weeks of MuGard therapy, and begin using MuGard one week prior to radiation treatment and then throughout the subsequent six weeks of planned therapy. The first 140 patients being treated in this assessment study have been enrolled and treated, and as of the time of the update, none of these patients have experienced any oral mucositis.

On July 7, 2009, we announced new preclinical data demonstrating that thiarabine shows remarkable efficacy in the prevention and treatment of rheumatoid arthritis (RA). In a well-established animal model for RA, an exceptional restoration of joint structure was observed in the studies, which were conducted at Wayne State University School of Medicine and at Southern Research Institute.

On June 17, 2009, we announced that we signed evaluation agreements with two biopharmaceutical companies for our Cobalamin<sup>™</sup> Oral Drug Delivery Technology. Under the terms of the agreements, both companies plan to evaluate Access' oral insulin product in preclinical models as a prerequisite to entering licensing discussions.

On February 25, 2009, we closed the previously announced acquisition of MacroChem Corporation.

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

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

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

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

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

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

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

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

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

### Patents

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

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

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



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

We have two patented Cobalamin-mediated targeted therapeutic technologies:

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

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

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

- · Mucoadhesive technology in 2021,
- ProLindac<sup>TM</sup> in 2021,
- · Thiarabine in 2018, and
- · Cobalamin mediated technology between 2009 and 2019

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

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

#### **Government Regulation**

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

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

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

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

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

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

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

#### Competition

The pharmaceutical and biotechnology industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and other product areas where we may develop and market products in the future. Most of our potential competitors are large, well established pharmaceutical, chemical or healthcare companies with considerably greater financial, marketing, sales and technical resources than are available to us. Additionally, many of our potential competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our product lines. Our potential products could be rendered obsolete or made uneconomical by the development of new products to treat the conditions to be addressed by our developments, technological advances affecting the cost of production, or marketing or pricing actions by one or more of our potential competitors. Our business, financial condition and results of operation could be materially adversely affected by any one or more of such developments. We cannot assure you that we will be able to compete successfully against current or future competitors or that competition will not have a material adverse effect on our business, financial condition and results of operation 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 or 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 ther products or the aware, or products or treatments that may be developed in the future, may adversely affect the marketability of products developed

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

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

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

The following products may compete with polymer platinate:

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

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

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

Thiarabine's competitors are Eli Lilly and Company, Bayer Healthcare, 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, Biovail Corporation, Cellgate, CIMA Labs, Inc., EUSA Pharma, Depomed Inc., Emisphere Technologies, Inc., Eurand, Flamel Technologies, Nobex and Xenoport are developing products which compete with our oral drug delivery system.

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

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

### **Suppliers**

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

### Employees

As of September 25, 2009, we had 9 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, our annual reports on Form 10-K and other reports that we file with the Securities and Exchange Commission as well as certain of our corporate governance policies, including the charters for the Board of Directors' audit, compensation and nominating and corporate governance committees and its code of ethics, corporate governance guidelines and whistleblower policy. We will also provide to any person without charge, upon request, a copy of any of the foregoing materials. Any such request must be made in writing to us at: Access Pharmaceuticals, Inc., 2600 Stemmons Freeway, Suite 176, Dallas, TX 75207 attn: Investor Relations.

# **DESCRIPTION OF PROPERTY**

Access maintains one facility of approximately 9,000 square feet for administrative offices and laboratories in Dallas, Texas. Access has a lease agreement for the facility, which terminates in December 2008. Adjacent space may be available for expansion which Access believes would accommodate growth for the foreseeable future.

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

## 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>	Age	<u>Title</u>
Steven H. Rouhandeh	52	Chairman of the Board
Jeffrey B. Davis	46	Chief Executive Officer, Director*
Esteban Cvitkovic	59	Vice Chairman – Europe
Mark J. Ahn, Ph.D.	47	Director
Mark J. Alvino	41	Director*
Stephen B. Howell, M.D.	65	Director
David P. Luci	42	Director
David P. Nowotnik, Ph.D.	60	Senior Vice President Research & Development
Phillip S. Wise	51	Vice President, Business Development & Strategy
Stephen B. Thompson	56	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.

No director, officer, affiliate or promoter of Access 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 director and executive officer of Access, 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, L.P., a New York based life sciences fund. Mr. Rouhandeh also is a founder of SCO Financial Group LLC, a highly successful value-oriented healthcare group with an 11-year track record in this sector (advisory, research, banking and investing). 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. Jeffrey B. Davis* became a director in March 2006. Mr. Davis became Chief Executive Officer of the Company 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.

*Dr. Esteban Cvitkovic* became a director in February 2007 as Vice Chairman (Europe) and is also a consultant to the Company as Senior Director, Oncology Clinical Research & Development. Recently, Dr. Cvitkovic co-founded the new contract research organization (CRO), Oncology Therapeutic Development. The oncology-focused CRO, Cvitkovic & Associés Consultants (CAC), founded by Dr. Cvitkovic 11 years ago and which he developed from a small oncology consultancy to a full-service CRO, was sold to AAIPharma to become AAIOncology in 2007. Dr. Cvitkovic is currently a Senior Medical Consultant to AAIOncology. 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. Mark J. Ahn* became a director in September 2006 and is a member of the Nominating & Corporate Governance Committee. Dr. Ahn is Professor and Chair, Science & Technology Faculties of Commerce & Administration Science at Victoria University of Wellington, New Zealand and has been in this position since September 2007. Dr. Ahn was President and Chief Executive Officer and a member of the board of directors of Hana Biosciences, Inc. from November 2003 to September 2007. Prior to joining Hana, from December 2001 to November 2003, he served as Vice President, Hematology and corporate officer at Genentech, Inc. where he was responsible for commercial and clinical development of the Hematology franchise. From February 1991 to February 1997 and from February 1997 to December 2001, Dr. Ahn was employed by Amgen and Bristol-Myers Squibb Company, respectively, holding a series of positions of increasing responsibility in strategy, general management, sales & marketing, business development, and finance. He has also served as an officer in the U.S. Army. Dr. Ahn is a Henry Crown Fellow at the Aspen Institute, founder of the Center for Non-Profit Leadership, a director of TransMolecular, Inc., a privately held biotechnology company focused on neuroncology, and a member of the Board of Trustees for the MEDUNSA (Medical University of South Africa) Trust. Dr. Ahn received a B.A. in History and an M.B.A. in Finance from Chaminade University. He was a graduate fellow in Economics at Essex University, and has a Ph.D. in Business Administration from the University of South Australia.

*Mr. Mark J. Alvino* became a director in March 2006 initially as a designee of SCO Capital Partners LLC and is 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 May 2007. Mr. Alvino was Managing Director for SCO Financial Group LLC from July 2002 to May 2007. Mr. Alvino was a member of the board of directors of MacroChem Corporation from May 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.

*Stephen B. Howell, M.D.* has served as one of Access' directors 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.

*Mr. David P. Luci* has served as one of Access' directors since January 2007 and is also chairman of the Audit and Finance Committee and a member of the Compensation Committee. As a result of consulting services provided by Mr. Luci to us, and our acquisition of MacroChem Corporation, where Mr. Luci previously served as an executive officer, Mr. Luci is no longer an independent director for board or audit committee purposes under NYSE Amex rules. Mr. Luci is currently a business consultant. Mr. Luci was President and Chief Business Officer of MacroChem Corporation until its merger with us on February 25, 2009. Additionally, Mr. Luci was a senior executive officer of Bioenvision, Inc. from July 2002 until August 2007. He served as Bioenvision's General Counsel & Corporate Secretary (2002-2007), Executive Vice President (2006-2007), Chief Financial Officer (2004-2006), and Director of Finance (2002-2004). From September 1994 to July 2002, Mr. Luci served as a corporate associate at Paul, Hastings, Janofsky & Walker LLP (New York office). Prior to that, Mr. Luci served as a senior auditor at Ernst & Young LLP (New York office). Mr. Luci is a certified public accountant. He holds a Bachelor of Science in Business Administration with a concentration in accounting from Bucknell University and a J.D. (cum laude) from Albany Law School of Union University.

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

*Mr. Phillip S. Wise* has been Access' 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 Vice President since 2000 and Access' 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 and Finance 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 and Finance Committee is currently comprised of David P. Luci (chairman). As a result of consulting services provided by Mr. Luci to us, and our acquisition of MacroChem Corporation, where Mr. Luci previously served as an executive officer, Mr. Luci is no longer an independent director for board or audit committee purposes under applicable SEC rules and NYSE Amex rules. The Board has determined that Mr. Luci, the chairman of the Audit and Finance Committee, is an "audit committee financial expert," under applicable SEC rules and regulations. The Audit and Finance 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 Compensation Committee is currently comprised of Mr. David P. Luci and Dr. Stephen B. Howell. Mr. Luci and Dr. Howell are nonemployee directors under applicable SEC rules, however, neither are "outside" directors under Internal Revenue Code Section 162(m). Mr. Luci and Dr. Howell are not independent under applicable NYSE Amex rules and regulations.

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 Access' corporate governance guidelines.

## **Code of Business Conduct and Ethics**

In October 2004, Access adopted a written Code of Business Conduct and Ethics for Employees, Executive Officers and Directors, applicable to all employees, management, and directors, designed to deter wrongdoing and promote honest and ethical conduct, full, fair and accurate disclosure, compliance with laws, prompt internal reporting and accountability to adherence to the Code of Business Conduct and Ethics.

## EXECUTIVE COMPENSATION

The following table sets forth the aggregate compensation paid to our CEO and each of our other executive officers whose aggregate salary and bonus exceeded \$100,000 for services rendered in all capacities for the fiscal years ended December 31, 2008 and 2007.

Summary Compensation Table

Name and Principal Position	<u>Year</u>	<u>Salary (\$)</u> (1)	<u>1</u>	<u>Option</u> Awards (\$) (2)	<u>C</u>	<u>All Other</u> ompensation (3)	<u>Total (\$)</u>
Jeffrey B. Davis (4) Chief Executive Officer	2008	\$ 266,076	\$	-	\$	-	\$ 266,076
David P. Nowotnik, Ph.D. Senior Vice President Research and Development	2008 2007	\$ 253,620 253,620	\$	136,977 -	\$	12,225 12,225	\$ 402,822 265,845
Phillip S. Wise Vice President, Business Development	2008 2007	\$ 200,000 200,000	\$	136,977 -	\$	9,876 \$ 9,876	\$ 346,853 209,876
Stephen B. Thompson Vice President, Chief Financial Officer	2008 2007	\$ 154,080 154,080	\$	136,977 -	\$	7,612 7,427	\$ 298,669 161,507

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

(2) The value listed in the above table represents the fair value of the options granted in prior years that was recognized in 2008 and 2007 under FAS 123R. 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 10 to our audited financial statements for the year ended December 31, 2008, included in our Annual Report on Form 10-K.

(3) Amounts reported for fiscal years 2008 and 2007 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.

(4) Jeffrey B. Davis became our Chief Executive Officer effective December 26, 2007 and his salary began to accrue as of the date of his employment agreement which was January 4, 2008.

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, 2008. There were no outstanding stock awards held by any such officers at December 31, 2008:

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	(2)	25,000	_		- 0.63	08/17/16
•		25,000	50.000			
David P. Nowotnik,	(3)	-	50,000		- 3.00	05/21/18
Ph.D.		100,000	-		0.63	08/17/16
		7,167	833		11.60	05/23/15
		5,000	-		29.25	01/23/14
		7,000	-		10.10	01/30/13
		10,000	-		18.65	03/22/12
		10,000	-		12.50	03/01/10
		10,000	-		10.00	07/20/09
Phillip S. Wise	(5)	-	50,000		- 3.00	05/21/18
		100,000			0.63	08/17/16
Stephen B. Thompson	(3)	-	50,000		- 3.00	05/21/18
		100,000	-		0.63	08/17/16
		4,479	521		11.60	05/23/15
		3,000	-		29.25	01/23/14
		4,000	-		10.10	01/30/13
		6,000	-		18.65	03/22/12
		9,000	-		12.50	03/01/10
		4,000	-		10.00	07/20/09

<sup>(1)</sup> On December 31, 2008, the closing price of our Common Stock as quoted on the OTC Bulletin Board was \$0.99.

- (2) Jeffrey B. Davis became our Chief Executive Officer effective December 26, 2007 and his 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 8,000 shares of common stock will be fully vested in April 2009. His options to purchase 50,000 shares of common stock will be fully vested in April 2012. His options to purchase 833 shares of common stock are fully vested in April 2009.
- <sup>(5)</sup> Mr. Wise's options to purchase 50,000 shares of common stock will be fully vested in April 2012.
- (4) Mr. Thompson's options to purchase 5,000 shares of common stock will be fully vested in April 2009. His options to purchase 50,000 shares of common stock will be fully vested in April 2012. His options to purchase 521 shares of common stock are fully vested in April 2009.

# **Compensation Pursuant to Agreements and Plans**

**Employment Agreements** 

### President and Chief Executive Officer

Access is a party to an employment agreement, with Jeffrey B. Davis, who was named by the Board as Access' 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 \$335,000 from January 4, 2008, through March 31, 2008, and was paid an annual salary of \$240,000 from April 1, 2008 until May 31, 2009. Mr. Davis is currently paid an annual salary of \$120,000 from June 1, 2009. Mr. Davis does not currently have any stock options resulting from his employment with us. Mr. Davis was previously awarded stock options to purchase 600,000 shares of our Common Stock. However, as of January 4, 2008, and pursuant to the amended employment agreement, Mr. Davis agreed to forgo any stock options awarded under the terms of the original employment agreement. Mr. Davis is entitled to similar employee benefits as Access' other executive officers.

#### Senior Vice President

Access was a party to an employment agreement with David P. Nowotnik, Ph.D., Access' Senior Vice President, Research and Development, until May 31, 2009. Under this agreement, Dr. Nowotnik was entitled to receive an annual base salary of \$253,620, subject to adjustment by the Board. Dr. Nowotnik was eligible to participate in all of Access' employee benefit programs available to executives. Dr. Nowotnik was also eligible to receive:

- a bonus payable in cash and Common Stock related to the attainment of reasonable performance goals specified by the Board;
- stock options at the discretion of the Board;
- · long-term disability insurance to provide compensation equal to at least \$60,000 annually; and
- term life insurance coverage of \$254,000.

On May 31, 2009 Dr. Nowotnik entered into a Transition Service Agreement with Access pursuant to which his current salary is \$10,000 per month until November 30, 2009. He was also granted options to purchase 75,000 shares of common stock at \$1.38, 12,500 of which options vest each month for six consecutive months. The transition services agreement continues provision for Dr. Nowotnik's healthcare coverage.

#### Vice President - Chief Financial Officer

Access was party to an employment agreement with Stephen B. Thompson, Access' Vice President and Chief Financial Officer, until May 31, 2009. Mr. Thompson was entitled to an annual base salary of \$154,080, subject to adjustment by the Board. The employment agreement also granted Mr. Thompson similar employee benefits as Access' other executive officers. Mr. Thompson was also eligible to receive:

- a bonus payable in cash and Common Stock related to the attainment of reasonable performance goals specified by the Board;
- stock options at the discretion of the Board;
- · long-term disability insurance to provide compensation equal to at least \$90,000 annually; and
- term life insurance coverage of \$155,000.

On May 31, 2009 Mr. Thompson entered into a Transition Service Agreement with Access pursuant to which his current salary is \$7,000 per month until November 30, 2009. He was also granted options to purchase 75,000 shares of common stock at \$1.38, 12,500 of which options vest each month for six consecutive months. The transition services agreement continues provision for Mr. Thompson's healthcare coverage.

#### **Compensation of Directors**

# Director Compensation Table - 2008

The table below represents the compensation paid to our outside directors during the year ended December 31, 2008:

Name	Fees earned or Paid in Cash (\$)	Stock Awards (\$)	Option Awards (\$) (1)	All Other Compensation (\$)	Total (\$)
Mark J. Ahn, PhD (2)	16,000	-	16,000	-	32,000
Mark J. Alvino (3)	16,000	-	16,000	-	32,000
Esteban Cvitkovic, MD (4)	12,000	-	180,000	350,000	542,000
Jeffrey B. Davis (5)	6,000	-	-	-	6,000
Stephen B. Howell, MD (6)	12,000	-	16,000	32,000	60,000
David P. Luci (7)	18,000	-	16,000	-	34,000
Rosemary Mazanet, MD, PhD (8)	7,000	-	126,000	-	133,000
John J. Meakem, Jr. (9)	10,000	-	9,000	-	19,000
Steven H. Rouhandeh (10)	10,000	-	-	-	10,000

<sup>(1)</sup> The value listed represents the fair value of the options recognized as expense under FAS 123R during 2008, including unvested options granted before 2008 and those granted in 2008. Fair value is calculated as of the grant date using a Black-Scholes ("Black-<sup>5</sup>) option-pricing model. The determination of the fair value of share-based payment awards made on the date of grant is Scholes 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 10 to our audited financial statements for the year ended December 31, 2008, included in our Annual Report on Form 10-K.

(2)Represents expense recognized in 2008 in respect of options to purchase 6,000 shares of our Common Stock based on a grant date fair value of \$16,000. Dr. Ahn has options to purchase 31,000 shares of our Common Stock at December 31, 2008. Represents expense recognized in 2008 in respect of options to purchase 6,000 shares of our Common Stock based on a grant date

(3) fair value of \$16,000. Mr. Alvino has options to purchase 31,000 shares of our Common Stock at December 31, 2008.

- (4)Represents expense recognized in 2008 in respect of warrants to purchase 100,000 shares of our Common Stock based on a fair value of \$164,000. Also represents expense recognized in 2008 in respect of options to purchase 6,000 shares of our Common Stock based on a grant date fair value of \$16,000. Includes \$350,000 Dr. Cvitkovic received for scientific consulting services in 2008. Dr. Cvitkovic has options to purchase 56,000 shares of our Common Stock and warrants to purchase 200,000 of our Common Stock at December 31, 2008.
- The fee included in this table was for board fees for the fourth quarter of 2007 paid in the first quarter of 2008. Mr. Davis served (5) as our CEO during 2008 and did not receive board fees. 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 has options to purchase 25,000 shares of our Common Stock at December 31, 2008.
- (6) Represents expense recognized in 2008 in respect of options to purchase 6,000 shares of our Common Stock based on a grant date fair value of \$16,000. Includes \$32,000 Dr. Howell received for scientific consulting services in 2008. Dr. Howell has options to purchase 44,700 shares of our Common Stock and warrants to purchase 2,000 of our Common Stock at December 31, 2008.
- Represents expense recognized in 2008 in respect of options to purchase 6,000 shares of our Common Stock based on a grant date (7)fair value of \$16,000. Mr. Luci has options to purchase 31,000 shares of our Common Stock at December 31, 2008.
- Represents expense recognized in 2008 in respect of options to purchase 50,000 shares of our Common Stock based on a grant date fair value of \$10,000; options to purchase 200,000 shares of our Common Stock based on a grant date fair value of \$25,000; (8)and an additional \$126,000 which represents the additional fair value of all Dr. Mazanet's vested options of which the exercise date was extended until May 25, 2010. Dr. Mazanet's term as a director expired on May 21, 2008.
- Includes \$9,000 which represents the additional fair value of all Mr. Meakem's vested options of which the exercise date was (9) extended until May 25, 2010. Mr. Meakem's term as a director expired on May 21, 2008.
- Mr. Rouhandeh does not have any options or warrants outstanding at December 31, 2008. See also the Security Ownership of (10)Certain Beneficial Owners and Management.

# **Equity Compensation Plan Information**

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

<u>Plan Category</u>	Number of securities to be issued upon exercise of outstanding options warrants and rights	Weighted-averag exercise price of outstanding option warrants and righ	compensation plans ns (excluding securities
Equity compensation plans approved by security holders 2005 Equity Incentive Plan 1995 Stock Awards Plan	1,136,820 118,000	\$ 1.º 15.	-
2001 Restricted Stock Plan Equity compensation plans not approved by security holders 2007 Special Stock Option Plan	- 100,000	2.	- 52,818 20 350,000
Total	1,354,820	\$ 3.	

For a description of our equity incentive plans, see Footnote [10] to our Consolidated Financial Statements for the fiscal year ended December 31, 2008.

# 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 Access, the following table sets forth certain information with respect to the beneficial ownership of Access' Common Stock as of October 26, 2009 by (i) each person who is known by Access to beneficially own more than five percent of any class of Access' capital stock; (ii) each of Access' directors; (iii) each of Access' named executive officers; and (iv) all Access' 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 Preferred Stock	Percent of Class	Amount and Nature of Beneficial Ownership Preferred Stock	Percent of Class	Amount and Nature of Beneficial Ownership All Classes of Stock	Percent of Class
Steven H. Rouhandeh <sup>(2)</sup>		*		*		*
	-		-		-	
Jeffery B. Davis <sup>(3)</sup>	36,000	*	-	*	36,000	*
Mark J. Ahn, Ph. D. <sup>(4)</sup>	66,000	*	-	*	66,000	*
Mark J. Alvino <sup>(5)</sup>	101,454	*	-	*	101,454	*
Esteban Cvitkovic, M.D. <sup>(6)</sup>	306,000	2.3%	-	*	306,000	1.3%
Stephen B. Howell, M.D. <sup>(7)</sup>	89,422	*	-	*	89,422	*
David P. Luci <sup>(8)</sup>	210,051	1.6%	8,333	*	218,384	*
David P. Nowotnik, Ph.D. <sup>(9)</sup>	251,268	1.9%	-	*	251,268	1.1%
Phillip S. Wise <sup>(10)</sup>	118,752	*	-	*	118,752	*
Stephen B. Thompson <sup>(11)</sup>	230,273	1.8%	-	*	230,273	1.0%
SCO Capital Partners LLC,						
SCO Capital Partners LP, and						
Beach Capital LLC (12)	9,535,087	50.2%	7,077,100	71.1%	16,612,187	57.4%
Larry N. Feinberg <sup>(13)</sup>	1,222,443	8.9%	1,457,699	14.7%	2,680,142	11.4%
Lake End Capital LLC <sup>(14)</sup>	1,059,601	7.8%	793,067	8.0%	1,852,668	7.8%
All Directors and Executive						
Officers as a group						
(consisting of 10 persons) (15)	1,409,220	9.9%	8,333	*	1,417,553	5.9%

\* - Less than 1%

(1) Includes Access' 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 October 26, 2009.

(2) Steven H. Rouhandeh is Chairman of SCO Securities LLC, a wholly-owned subsidiary of SCO Financial Group LLC. His address is c/o SCO Capital Partners LLC, 1285 Avenue of the Americas, 35th Floor, New York, NY 10019. SCO Securities LLC and affiliates (SCO Capital Partners LP and Beach Capital LLC) are known to beneficially own an aggregate of 3,481,800 shares of Access' Common Stock, warrants to purchase an aggregate of 6,053,287 shares of Access' Common Stock and 7,077,100 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 is known to beneficially own an aggregate of 7,333 shares of Access' Common Stock, presently exercisable options for the purchase of 25,000 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan and 3,667 shares of Common Stock underlying warrants held by Mr. Davis. Mr. Davis is President of SCO Securities LLC, a wholly-owned subsidiary of SCO Financial Group LLC. His address is c/o SCO Capital Partners LLC, 1285 Avenue of the Americas, 35th Floor, New York, NY 10019. SCO Securities LLC and affiliates (SCO Capital Partners LP and Beach Capital LLC) are known to beneficially own 3,481,800 shares of Access' Common Stock, warrants to purchase an aggregate of 6,053,287 shares of Access' Common Stock and 7,077,100 shares of Common Stock issuable upon conversion of Series A Cumulative Convertible Preferred Stock. Mr. Davis disclaims beneficial ownership of all such shares except to the extent of his pecuniary interest therein.

- (4) Includes presently exercisable options for the purchase of 66,000 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan.
- (5) Includes 35,454 shares of Common Stock underlying warrants held by Mr. Alvino and presently exercisable options for the purchase of 66,000 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan. Mr. Alvino is Managing Director of Griffin Securities LLC. His address is c/o Griffin Securities LLC, 17 State St., 3<sup>rd</sup> Floor, New York, NY 10004. Mr. Alvino is a designated director of SCO Securities LLC. SCO Securities LLC and affiliates (SCO Capital Partners LP and Beach Capital LLC) are known to beneficially own 3,481,800 shares of Access' Common Stock, warrants to purchase an aggregate of 6,053,287 shares of Access' Common Stock and 7,077,100 shares of Common Stock issuable upon conversion of Series A Cumulative Convertible Preferred Stock. Mr. Alvino disclaims beneficial ownership of all such shares except to the extent of his pecuniary interest therein. Mr. Alvino disclaims beneficial ownership of all such shares except to the extent of his pecuniary interest therein.
- (6) Includes presently exercisable options for the purchase of 156,000 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan and a warrant to purchase 150,000 shares of Access' Common Stock at an exercise price of \$3.15 per share. Dr. Cvitkovic has also been granted an additional warrant of 50,000 shares of Access' Common Stock at an exercise price of \$3.15 that vests January 1, 2010.
- (7) Dr. Howell is known to beneficially own an aggregate of 9,722 shares of Access' Common Stock, presently exercisable options for the purchase of 67,200 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan and 12,500 shares of Access' Common Stock pursuant to the 1995 Stock Option Plan.
- (8) Mr. Luci is known to beneficially own an aggregate of 129,884 shares of Access' Common Stock, warrants to purchase an aggregate of 4,167 shares of Access' Common Stock, 8,333 shares of Common Stock issuable to him upon conversion of Series A Cumulative Convertible Preferred Stock and presently exercisable options for the purchase of 76,000 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan. Mr. Luci has also been granted 66,666 restricted shares of Access' Common Stock that vests on January 1, 2010 and 66,666 restricted shares of Access' Common Stock that vests on June 1, 2010.
- (9) Dr. Nowotnik is known to beneficially own an aggregate of 17,516 shares of Access' Common Stock, presently exercisable options for the purchase of 193,752 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan and 40,000 shares of Access' Common Stock pursuant to the 1995 Stock Option Plan.
- (10) Includes presently exercisable options for the purchase of 118,752 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan.
- (11) Mr. Thompson is known to beneficially own an aggregate of 9,521 shares of Access' Common Stock, presently exercisable options for the purchase of 193,752 shares of Access' Common Stock pursuant to the 2005 Equity Incentive Plan and 27,000 shares of Access' Common Stock pursuant to the 1995 Stock Option Plan.
- (12) SCO Capital Partners LLC, SCO Capital Partner LP, Beach Capital LLC and SCO Financial Group's address is 1285 Avenue of the Americas, 35<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 3,481,800 shares of Access' Common Stock, warrants to purchase an aggregate of 6,053,287 shares of Access' Common Stock and 7,077,100 shares of Common Stock issuable upon conversion of Series A Cumulative Convertible Preferred Stock. Each of Mr. Rouhandeh, Mr. Davis and Mr. Alvino, 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.
- (13) 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 Access' Common Stock, warrants to purchase an aggregate of 728,850 shares of Access' Common Stock and Series A Cumulative Convertible Preferred Stock which may be converted into an aggregate of 1,457,699 shares of Access' Common Stock.
- (14) Lake End Capital LLC's address is 1285 Avenue of the Americas, 35 <sup>th</sup> Floor, New York, NY 10019. Lake End Capital LLC is known to beneficially own an aggregate of 335,575 shares of Access' Common Stock, warrants to purchase an aggregate of 724,026 shares of Access' Common Stock and 793,067 shares of Common Stock issuable to them upon conversion of Series A Cumulative Convertible Preferred Stock.
- (15) Does not include shares held by SCO Securities LLC and affiliates.

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

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

On February 12, 2008, the Board of Directors of the Company elected Steven H. Rouhandeh as director and Chairman of the Board effective as of March 4, 2008. Mr. Rouhandeh is Chief Investment Officer of SCO Capital Partners, L.P. In the event SCO Capital Partners LLC ("SCO") and its affiliates were to convert all of their shares of Series A Cumulative Convertible Preferred Stock and exercise all of their warrants, they would own approximately 59.0% of the voting securities of Access. During 2008 SCO and affiliates were paid \$191,000 in placement agent fees relating to the issuance of preferred stock and were issued warrants to purchase 39,667 shares of our common stock. During 2007 SCO and affiliates were paid \$240,000 in placement agent fees relating to the issuance of our Common Stock. SCO and affiliates also were paid \$232,000 in investor relations fees in 2008 and \$150,000 in investor relations fees in 2007.

On February 25, 2009 we closed our acquisition of MacroChem Corporation. In connection with the merger, Access issued an aggregate of approximately 2.5 million shares of Access Pharmaceuticals, Inc. common stock to the holders of MacroChem common stock and in-themoney warrant holders as consideration, having a value of approximately \$3,500,000 (the value was calculated using Access' stock price on February 25, 2009, times the number of shares issued).

In addition, on February 25, 2009, we issued 859,172 shares of our unregistered common stock to the holders of \$825,000 of MacroChem notes and interest in exchange for cancellation of those notes. We also issued 60,000 shares of our unregistered common stock in exchange for the settlement and release agreement with David P. Luci, Chief Business Officer of MacroChem Corporation. Mr. Luci is a director of Access. Additionally, on February 25, 2009 we issued 35,000 shares of our unregistered common stock in exchange for the cancellation of employment agreements to two former executives of MacroChem. The securities issued to the former MacroChem noteholders and the former executives were issued under section 4(2) of the Securities Act, as amended.

Prior to our acquisition of MacroChem Corporation, SCO and its affiliates and Lake End Capital LLC owned approximately 63% of MacroChem.

In connection with the sale and issuance of Series A Cumulative Convertible 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 directors appointed by SCO pursuant to this arrangement were Jeffrey B. Davis, our Chief Executive Officer, and Mr. Mark Alvino.

David P. Luci, one of our directors, participated in the February 2008 sale of our preferred stock. Mr. Luci purchased 2.5 preferred shares for \$25,000 and warrants to purchase 4,167 shares of our common stock. In addition, Mr. Luci was the President & Chief Business Officer of MacroChem, which we acquired on February 25, 2009, pursuant to a Merger Agreement dated July 9, 2008. We signed an amended Consulting, Settlement and Release Agreement with Mr. Luci on March 16, 2009 where he received 60,000 shares of our restricted common stock and \$27,500 in a one time cash payment to settle his rights under a previous consulting agreement with MacroChem. On June 1, 2009 we signed a consulting agreement with Mr. Luci where Mr. Luci will provide consulting services to Access for cash compensation of \$9,415 per month and for 200,000 shares of our restricted common stock and a cash bonus if certain events occur, as defined in the agreement. The 200,000 shares of restricted common stock vests 66,667 shares on June 1, 2009, 66,666 shares on January 1, 2010 and 66,667 shares on June 1, 2010.

Dr. Esteban Cvitkovic, a Director, has served as a consultant and Senior Director, Oncology Clinical Research & Development, since August 2007. Dr. Cvitkovic currently receives \$20,000 per month plus \$2,500 for office expenses. During 2008, Dr. Cvitkovic received \$350,000 from us for consulting services. In January 2008, Dr. Cvitkovic also received for his consulting services, warrants to purchase 200,000 shares of our Common Stock which warrants can be exercised until January 4, 2012. The warrants vest over two years in 50,000 share blocks with vesting on July 4, 2008, January 4, 2009, July 4, 2009, and the remaining shares on January 4, 2010. Dr. Cvitkovic is a principal of OTD Oncology Therapeutic Development, a clinical research organization which has been working with the Company on the clinical development of ProLindac.

Mr. Alvino is a principal of Griffin Securities which maintains a banking relationship with the Company.

Stephen B. Howell, M.D., a Director, received payments for consulting services and reimbursement of direct expenses. His consulting agreement expired in March 1, 2008. Dr. Howell was paid \$32,000 in 2008 in consulting fees.

On October 12, 2000, the Board authorized a restricted stock purchase program. Under the program, our executive officers were given the opportunity to purchase shares of Common Stock in an individually designated amount per participant determined by our Compensation Committee. A total of 36,000 shares were purchased by such officers at \$27.50 per share, the fair market value of the Common Stock on October 12, 2000, for an aggregate consideration of \$990,000. The purchase price was paid through the participant's delivery of a 50%-recourse promissory note payable to us. Each note bears interest at 5.87% compounded semi-annually and has a maximum term of ten years. The notes are secured by a pledge to us of the purchased shares. We recorded the notes receivable of \$990,000 from participants in this program as a reduction of equity in the Consolidated Balance Sheet. As of December 31, 2008, principal and interest on the notes was: Mr. Gray - \$908,000; Dr. Nowotnik - \$454,000; and Mr. Thompson - \$272,000. In accordance with the Sarbanes-Oxley Act of 2002, we no longer make loans to our executive officers. Interest on the notes is neither being collected nor accrued.

68

#### **DESCRIPTION OF SECURITIES**

Access' certificate of incorporation authorizes the issuance of 100,000,000 shares of its common stock, \$.01 par value per share, and 2,000,000 shares of preferred stock, \$.01 par value per share, which may be issued in one or more series. Currently, 4,000 shares of preferred stock are designated as Series A Cumulative Convertible Preferred Stock and 300,000 are designated as Series A Junior Participating Preferred Stock. As of October 26, 2009 there were 13,115,545 shares of Access' common stock outstanding and held of record by approximately 10,900 stockholders, and there were 2,992.3617 shares of its Series A Cumulative Convertible Preferred 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 \$3.00 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 gives 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 \$3.00 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.

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.

#### Warrants

As of October 26, 2009, warrants for the issuance of 9,835,479 shares of our common stock were outstanding, all of which are exercisable at a weighted average exercise price of \$2.81 per share, all of which are exercisable through various dates expiring between June 9, 2010 and July 23, 2014.

The descriptions of the warrants are only a summary and are qualified in their entirety by the provisions of the forms of the warrant, which are attached or referenced to the registration statement of which this prospectus forms a part.

#### **Unit Warrants**

In connection with this offering, we will issue warrants to purchase up to \_\_\_\_\_\_\_\_ shares of common stock. Each warrant entitles the holder to purchase one share of common stock at an exercise price of \$\_\_\_\_\_\_ per share. After the expiration of the exercise period, unit warrant holders will have no further rights to exercise such unit warrants.

The unit warrants may be exercised only for full shares of common stock, and may be exercised on a "cashless" basis. If the registration statement covering the shares issuable upon exercise of the warrants contained in the units is no longer effective, the unit warrants may only be exercised on a "cashless" basis and will be issued with restrictive legends unless such shares are eligible for sale under Rule 144. We will not issue fractional shares of common stock or cash in lieu of fractional shares of common stock. Unit warrant holders do not have any voting or other rights as a stockholder of our company. The exercise price and the number of shares of common stock purchasable upon the exercise of each unit warrant are subject to adjustment upon the happening of certain events, such as stock dividends, distributions, and splits.

Certain institutional investors are prohibited, pursuant to their investment charter or other governing documents, from acquiring warrants. Accordingly, we and the placement agent may, upon request of any such investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants will be at a price per unit equal to \$\_\_\_\_\_.

70

## **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.

#### PLAN OF DISTRIBUTION

We are offering up to \_\_\_\_\_\_ units, each consisting of \_\_\_ shares of common stock and warrants to purchase an additional \_\_\_ shares of common stock for \$\_\_\_ per unit. Pursuant to an engagement letter agreement, we engaged \_\_\_\_\_\_ as our placement agent for this offering. \_\_\_\_\_\_ [Placement Agent] is not purchasing or selling any units, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of units, other than to use their "best efforts" to arrange for the sale of units by us. Therefore, we may not sell the entire amount of units being offered.

Upon the closing of the offering, we will pay the placement agent a cash transaction fee equal to <u>%</u> of the gross proceeds to us from the sale of the units in the offering. At the closing of the sale of any units contained in the over allotment option, we will pay the placement agent a cash transaction fee equal to <u>%</u> of the gross proceeds to us from any such closing.

We and the placement agent may, upon request of any investor in this offering, sell units to such investors that exclude the warrants, provided that the sale of units that exclude such warrants shall be at the same offering price per unit as all other investors.

In addition, we agreed to grant a five-year compensation warrant to the placement agent to purchase a number of shares of our common stock equal to  $\_\%$  of the number of shares of common stock contained in the units sold by us in the offering, including any units sold upon exercise of the over allotment option, but excluding the shares that may be issued upon exercise of the warrants included in the offering. The compensation warrants will have an exercise price equal to the exercise price of warrants granted to the investors in the offering and will be substantially on the same terms as the warrants included in the offering, except that the compensation warrants will comply with FINRA Rule 5110(g)(1) in that for a period of six months after the issuance date of the compensation warrants (which shall not be earlier than the closing date of the offering pursuant to which the compensation warrants are being issued), neither the compensation warrants nor any warrant shares issued upon exercise of the compensation 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 the offering pursuant to which the compensation that would result in the effective essent of sales of the offering pursuant to which the compensation that would result in the effective essent of sales of the offering pursuant to which the compensation that would result in the effective essent of sales of the offering pursuant to which the compensation warrants are being issued, except the transfer of any security as permitted by FINRA rules.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any commissions received by it and any profit realized on the sale of the securities by them while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent would be required to comply with the requirements of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of shares of common stock and warrants to purchase shares of common stock by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

The placement agent agreement provides that we will indemnify the placement agent against specified liabilities, including liabilities under the Securities Act. We have been advised that, in the opinion of the Securities and Exchange Commission, indemnification for liabilities under the Securities Act is against public policy as expressed in the Securities Act and is therefore unenforceable. The placement agent agreement also provides that the agreement may be terminated by either party upon thirty (30) days prior written notice.

73

#### Notice to Investors in the United Kingdom

This prospectus is being distributed only to, and is only directed at (i) persons who are outside the United Kingdom, or (ii) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (e) of the Order, or (iv) persons to whom Article 33 of the Order applies (all such persons being referred to as "relevant persons" and each a "relevant person"). Accordingly, by accepting delivery of this prospectus, the recipient warrants and acknowledges that it is such a relevant person and where Article 33 of the Order applies it acknowledges that it has previously been advised (a) that the protections conferred by the Financial Services and Markets Act 2000 (the "Act") will not apply to any communication in relation to the securities the subject of this prospectus; and (b) that the protections conferred by or under the Act may not apply to any investment activity that may be engaged in as a result of any such communication. The securities are only available to, and any invitation, offer, or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with relevant persons. Any person who is not a relevant person should not act or rely on tis prospectus or any of its contents.

This prospectus has not bee approved by an authorized person in the United Kingdom. No person may communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of Section 21(1) of the Act) received by it in connection with the issue or sale of the securities other than in circumstances in which Section 21(1) of the Act does not apply to us.

#### **European Economic Area**

In particular, this document does not constitute an approved prospectus in accordance with European Commission's Regulation on Prospectuses no. 809/2004 and no such prospectus is to be prepared and approved in connection with this offering. Accordingly, in relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (being the Directive of the European Parliament and of the Council 2003/71/EC and including any relevant implementing measure in each Relevant Member State) (each, a Relevant Member State), with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) an offer of securities to the public may not be made 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 Relative Implementation Date, make an offer of 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 euros; and (3) an annual net turnover of more than 50,000,000 euros, as shown in the last annual or consolidated accounts; or
- in any other circumstances which do not require the publication by the Issuer of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer of securities to the public" in relation to any shares 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 the shares, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State. For these purposes the units are "securities."

Each of our executive officers and directors reside in and are citizens of the United States except as follows:

74

Dr. Esteban Citkovic, our Vice Chairman, resides in and is a citizen of France; and

Dr. David Nowotnik, our Senior Vice President, Research and Development, is a permanent resident of the United States but is a citizen of the United Kingdom.

# **Abandoned Private Placement**

Between July 2009 and October 15, 2009, we were engaged in preliminary discussions with a number of potential investors, both directly and through registered broker-dealers, concerning a possible private placement of an unspecified amount of shares of our common stock or other equity securities. We and any person acting on our behalf offered securities only to persons that were, or that we reasonably believed to be, accredited investors, as defined in Regulation D under the Securities Act of 1933, as amended. The private placement was intended to be completed in reliance upon Rule 506 of Regulation D. On October 15, 2009, we abandoned the private placement and all offering activity in connection therewith was terminated in order to enable us to pursue this offering. No offers to buy or indications of interest given in the private placement discussions were accepted. This prospectus supersedes any offering materials used in the abandoned private placement.

#### EXPERTS

The consolidated financial statements of Access for the years ended December 31, 2008 and 2007 included in this prospectus, and included in the Registration Statement, were audited by Whitley Penn LLP, an independent registered public accounting firm, as stated in their report appearing with the consolidated financial statements herein and incorporated in this Registration Statement, and are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

The consolidated financial statements of MacroChem Corporation for the year ended December 31, 2008 included in this prospectus, and included in the Registration Statement, were audited by Whitley Penn LLP, an independent registered public accounting firm, as stated in their report appearing with the consolidated financial statements herein and incorporated in this Registration Statement, and are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

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

## LEGAL MATTERS

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

#### WHERE YOU CAN FIND MORE INFORMATION

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

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

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

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

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

76

# FINANCIAL STATEMENTS ACCESS PHARMACEUTICALS, INC.

	PAGE
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets at December 31, 2008 and 2007	F-3
Consolidated Statements of Operations for 2008 and 2007	F-4
Consolidated Statements of Stockholders' Equity (Deficit) for 2008 and 2007	F-5
Consolidated Statements of Cash Flows for 2008 and 2007	F-6
Notes to Consolidated Financial Statements (Two years ended December 31, 2008)	F-7
Condensed Consolidated Balance Sheets at June 30, 2009 (unaudited)	F-25
Condensed Consolidated Statements of Operations for June 30, 2009 and 2008 (unaudited)	F-26
Condensed Consolidated Statement of Stockholders' Deficit for June 30, 2009 (unaudited)	F-27
Condensed Consolidated Statements of Cash Flows for June 30, 2009 and 2008 (unaudited)	F-28
Notes to Condensed Consolidated Financial Statements (Three Months Ended June 30, 2009 and 2008) (unaudited)	F-29

#### **Report of Independent Registered Public Accounting Firm**

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

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

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

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

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

/s/ WHITLEY PENN LLP

Dallas, Texas March 31, 2009



# CONSOLIDATED BALANCE SHEETS

ASSETS	December 31, 2008	December 31, 2007
Current assets Cash and cash equivalents Receivables Receivables due from MacroChem Corp.	\$ 2,663,000 147,000 635,000	\$ 6,921,000 35,000
Receivables due from Somanta Pharmaceuticals, Inc. Prepaid expenses and other current assets	105,000	931,000 410,000
Total current assets	3,550,000	8,297,000
Property and equipment, net	87,000	130,000
Patents, net	542,000	710,000
Other assets	78,000	12,000
Total assets LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT) Current liabilities	\$ 4,257,000	\$ 9,149,000
Accounts payable Accrued expenses Dividends payable Accrued interest payable Current portion of deferred revenue Current portion of convertible long-term debt	\$ 1,970,000 748,000 1,896,000 128,000 164,000	
Total current liabilities	4,906,000	2,058,000
Long-term deferred revenue Long-term convertible debt Total liabilities	2,245,000 5,500,000 12,651,000	910,000 5,500,000 8,468,000
Commitments and contingencies		
<ul> <li>Stockholders' equity (deficit)</li> <li>Convertible preferred stock - \$.01 par value; authorized 2,000,000 shares; 3,242.8617 issued at December 31, 2008; 3,227.3617 issued at December 31, 2007</li> <li>Common stock - \$.01 par value; authorized 100,000,000 shares; issued, 6,967,474 at December 31, 2008; issued 3,585,458 at December 31, 2007</li> <li>Additional paid-in capital</li> <li>Notes receivable from stockholders</li> <li>Treasury stock, at cost – 163 shares</li> <li>Accumulated deficit</li> <li>Total stockholders' equity (deficit)</li> </ul>	70,000 127,482,000 (1,045,000) (4,000) (134,897,000) (8,394,000)	36,000 116,018,000 (1,045,000) (114,324,000) (114,324,000) 681,000
Total liabilities and stockholders' equity (deficit)	\$ 4,257,000	\$ 9,149,000

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

# CONSOLIDATED STATEMENTS OF OPERATIONS

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

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

# CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

	Commo	Common Stock Preferred Stock		Additional paid-in	Notes receivable from	Treasury	Accumulated		
	Shares	Amount	Shares	Amount	capital	stockholders	stock	deficit	
Balance, December 31, 2006	3,535,000	\$ 35,000		\$ -	\$68,799,000	\$ (1,045,000) \$	§ (4.000)	\$ (77,672,000)	
Common stock issued	5,555,000	\$ 55,000		Ψ	\$00,777,000	\$ (1,010,000) C	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	\$ (11,012,000)	
for services	19,000	-	-	-	83,000	-	-	-	
Options exercised	31,000	1,000	-	-	35,000	-	-	-	
Stock option compensation expense	-	-	-	-	1,048,000	-	-	-	
Preferred stock issuances Warrants issued with	-	-	954.0001	-	5,560,000	-	-	-	
preferred stock	-	-	-	-	3,980,000	-	-	-	
Costs of stock issuances Beneficial conversion					(868,000)	-	-	-	
feature	-	-	-	-	14,648,000	-	-	-	
Preferred stock dividend beneficial conversion								(14 (49 000))	
feature Conversion of	-	-	-	-	-	-	-	(14,648,000)	
convertible debt into preferred									
stock Warrants issued with	-	-	2,273.3616	-	6,472,000	-	-	-	
preferred stock	-	-	-	-	4,633,000	-	-	-	
Loss on extinguishment of debt – preferred									
stock Loss on extinguishment	-	-	-	-	6,777,000	-	-	-	
of debt – warrants	-	-	-	-	4,851,000	-	-	-	
Preferred dividends Net loss	-	-	-	-	-	-	-	(260,000) (21,744,000)	
Balance, December 31, 2007	3,585,000	36,000	3,227.3617	-	116,018,000	(1,045,000)	(4,000)	(114,324,000)	
Common stock issued for									
services Warrants issued for	10,000	-	-	-	27,000	-	-	-	
services	-	-	-	-	350,000	-	-	-	
Options exercised Stock option	25,000	-	-	-	15,000	-	-	-	
compensation expense Preferred stock	-	-	-	-	415,000	-	-	-	
issuances	-	-	272.5000	-	1,687,000	-	-	-	
Warrants issued with preferred stock	-	-	-	-	1,142,000	-	-	-	
Costs of stock issuances Preferred stock dividend	-	-	-	-	(385,000)	) -	-	-	
beneficial conversion	_	_	_	_	1,308,000	_	_	(1,308,000)	
feature Common stock and	-	-	-	-	1,508,000	-	-	(1,508,000)	
warrants issued to Somanta shareholders Common stock and	1,500,000	15,000	-	-	4,916,000	-	-	-	
warrants issued to Somanta creditors	538,000	5,000	-	-	1,571,000	-	-	-	
Preferred stock converted		·			-				
into common stock Common stock issued	857,000	9,000	(257.0000)	) -	(9,000)	) -	-	-	
for preferred dividends	452,000	5,000	-	-	427,000	-	-	-	
Preferred dividends Net loss	-	-	-	-	-	-	-	(2,050,000) (17,215,000)	
Balance, December 31, 2008									

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

# CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,				
	2008		2007		
Cash flows from operating activities:					
Net loss	\$ (17,215,000)	\$	(21,744,000)		
Adjustments to reconcile net loss to net cash used					
in operating activities:			11 (29,000		
Loss on extinguishment of debt	-		11,628,000		
Stock option expense	415,000		1,048,000		
Stock and warrants issued for services	377,000		83,000		
Acquired in-process research & development	8,879,000		-		
Depreciation and amortization	253,000		279,000		
Amortization of debt costs and discounts	-		2,316,000		
Loss on sale of assets	-		2,000		
Change in operating assets and liabilities:					
Receivables	(747,000)		(607,000)		
Prepaid expenses and other current assets	(80,000)		(127,000)		
Other assets	(66,000)		14,000		
Accounts payable and accrued expenses	176,000		310,000		
Dividends payable	19,000		-		
Accrued interest payable	(2,000)		1,150,000		
Deferred revenue	1,431,000		805,000		
Net cash used in operating activities	(6,560,000)	-	(4,843,000)		
Cash flows from investing activities:					
Capital expenditures	(28,000)		(18,000)		
Somanta acquisition, net of cash acquired	(65,000)		-		
Proceeds from sale of asset	-		13,000		
Net cash used in investing activities	(93,000)		(5,000)		
Cash flows from financing activities:					
Payments of notes payable	(64,000)		(1,327,000)		
Proceeds from preferred stock issuances, net of costs	2,444,000		8,672,000		
Proceeds from exercise of stock options	15,000		35,000		
•					
Net cash provided by financing activities	2,395,000		7,380,000		
Net increase (decrease) in cash and cash equivalents	(4,258,000)		2,532,000		
Cash and cash equivalents at beginning of year	6,921,000		4,389,000		
Cash and cash equivalents at end of year	\$ 2,663,000	\$	6,921,000		
Cash and cash equivalents at one of year	φ2,003,000	Ψ	0,721,000		
Supplemental cash flow information:					
Cash paid for interest	\$ 435,000	\$	34,000		
Supplemental disclosure of noncash transactions					
Shares issued for payables	1,576,000		-		
Preferred stock dividends in dividends payable	1,896,000		260,000		
Accrued interest capitalized			511,000		
Warrants issued for placement agent fees	104,000		523,000		
Beneficial conversion feature -	101,000		525,000		
February 2008 preferred stock dividends	857,000		_		
November 2007 preferred stock dividends	451,000		14,648,000		
Preferred stock issuance costs paid in cash	281,000		345,000		
Debt exchanged for preferred stock	281,000		10,015,000		
Accrued interest exchanges for preferred stock	-		1,090,000		
Stock issued for preferred dividends	432,000		1,090,000		
Stock issued for prejerred dividends	432,000		-		

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

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

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

#### Nature of Operations

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

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

#### Principles of Consolidation

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

#### **Reclassifications**

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

#### Use of Estimates

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

#### Segments

The Company operates in a single segment.

#### Cash and Cash Equivalents

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

#### Property and Equipment

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



#### Research and Development Expenses

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

#### Fair Value of Financial Instruments

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

#### Income Taxes

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

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

#### Loss Per Share

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

#### Patents

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

Intangible assets consist of the following (in thousands):

		December 31, 2008				Decembe	er 31,	2007
	(	Gross			(	Gross		
	ca	carrying Accumulated		ca	rrying	Acc	umulated	
		value	amor	tization		value	amo	rtization
Amortizable intangible assets - Patents	\$	1,680	\$	1,138	\$	1,680	\$	970

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

2009	\$ 168
2010	168
2011	168
2012	38
Total	\$ 542

#### **Revenues**

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

#### Stock-Based Compensation

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

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

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

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

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

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

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

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

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

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

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

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

# Recent Accounting Pronouncements

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

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

### **NOTE 2 – LIQUIDITY**

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

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

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

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

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

On November 7, 2007, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 954.0001 shares of a newly created series of our preferred stock, designated "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series A Preferred Stock") and agreed to issue warrants to purchase 1,589,999 shares of our common stock at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Preferred Stock and Warrants of \$9,540,001. The shares of Series A Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share.

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

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

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

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

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

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

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

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

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

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

# **NOTE 4 - PROPERTY AND EQUIPMENT**

Property and equipment consists of the following:	December 31,			1,
		2008		2007
Laboratory equipment	\$	31,000	\$	824,000
Laboratory and building improvements		58,000		58,000
Furniture and equipment		75,000		40,000
		964,000		922,000
Less accumulated depreciation and amortization		877,000		792,000
Net property and equipment	\$	87,000	\$	130,000

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

# NOTE 5 - 401(k) PLAN

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

### NOTE 6 – DEBT

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

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

On November 7, 2007, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 954.0001 shares of a newly created series of our preferred stock, designated "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series A Preferred Stock") and agreed to issue warrants to purchase 1,589,999 shares of our common stock at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Preferred Stock and Warrants of \$9,540,000. The shares of Series A Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share.

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

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

# NOTE 7 – COMMITMENTS AND CONTINGENCIES

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

Debt

5,500,000

Future Maturities 2011

## Operating Leases

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

# <u>Legal</u>

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

# **NOTE 8 – PREFERRED STOCK**

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

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

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

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

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

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

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

On November 7, 2007, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 954.0001 shares of a newly created series of our preferred stock, designated "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series A Preferred Stock") and agreed to issue warrants to purchase 1,589,999 shares of our common stock at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Preferred Stock and Warrants of \$9,540,001. The shares of Series A Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share.

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

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

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

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

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

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

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

#### NOTE 9 - STOCKHOLDERS' EQUITY

#### Restricted Stock Purchase Program

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

#### Warrants

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

	Warrants	Exercise	Expiration
Summary of Warrants	Outstanding	Price	Date
2008 preferred stock offering (a)	499,584 \$	3.50	2/24/14
2008 Somanta accounts payable (b)	246,753	3.50	1/04/14
2008 Warrants assumed on acquisition (c)	191,991	18.55-69.57	6/9/10-1/31/12
2008 investor relations advisor (d)	50,000	3.15	1/3/13
2008 investor relations advisor (e)	40,000	3.00	9/1/13
2008 scientific consultant (f)	200,000	3.15	1/4/12
2007 preferred stock offering (g)	3,649,880	3.50	11/10/13
2006 convertible note (h)	3,863,634	1.32	2/16/12
2006 convertible note (h)	386,364	1.32	10/24/12
2006 convertible note (h)	386,364	1.32	12/06/12
2006 investor relations advisor (i)	50,000	2.70	12/27/11
2004 offering (j)	89,461	35.50	2/24/09
2004 offering (j)	31,295	27.00	2/24/09
2002 scientific consultant (k)	2,000	24.80	2/01/09
Total	9,687,326		

- a) In connection with the preferred stock offering in February 2008, warrants to purchase a total of 499,584 shares of common stock were issued. All of the warrants are exercisable immediately and expire six years from date of issue. The fair value of the warrants was \$2.29 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.75%, expected volatility 110% and a term of 6 years.
- b) In exchange for \$1,576,000 due Somanta vendors, the vendors were given 538,508 shares of common stock and warrants to purchase 246,753 shares of common stock at \$3.50. The warrants expire January 4, 2014.

- c) We assumed three warrants in the Somanta acquisition:
  -Warrant#1 323 shares of our common stock at \$69.57 per share and expires June 9, 2010.
  -Warrant #2 31,943 shares of our common stock at \$18.55 per share and expires January 31, 2012.
  -Warrant #3 159,725 shares of our common stock at \$23.19 per share and expires January 31, 2012.
- d) During 2008, an investor relations advisor received warrants to purchase 50,000 shares of common stock at an exercise price of \$3.15 per share at any time until January 3, 2013, for investor relations consulting services to be rendered in 2008. 25,000 of the warrants were exercisable on July 3, 2008 and 25,000 of the warrants will be exercisable January 3, 2009. The fair value of the warrants was \$2.24 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.13%, expected volatility 127% and a term of 5 years.
- e) During 2008, an investor relations advisor received warrants to purchase 40,000 shares of common stock at an exercise price of \$3.00 per share at any time until September 1, 2013, for investor relations consulting services. All of the warrants are exercisable. The fair value of the warrants was \$2.61 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.37%, expected volatility 132% and a term of 5 years.
- f) During 2008, a director who is also a scientific advisor received warrants to purchase 200,000 shares of common stock at an exercise price of \$3.15 per share at any time until January 4, 2012, for scientific consulting services rendered in 2008. The warrants vest over two years in 50,000 share blocks with vesting on July 4, 2008, January 4, 2009, July 4, 2009 and the remaining shares on January 4, 2010. The fair value of the warrants was \$1.78 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 2.01%, expected volatility 92% and a term of 4 years.
- g) In connection with the preferred stock offering in November 2007, warrants to purchase a total of 3,649,880 shares of common stock were issued. All of the warrants are exercisable immediately and expire six years from date of issue. The fair value of the warrants was \$2.50 per share on the date of the grant using the Black-Scholes pricing model with the following assumptions: expected dividend yield 0.0%, risk-free interest rate 3.84%, expected volatility 114% and a term of 6 years.
- h) In connection with the convertible note offerings in 2006, warrants to purchase a total of 4,636,362 shares of common stock were issued. All of the warrants are exercisable immediately and expire six years from date of issue.
- i) During 2006, an investor relations advisor received warrants to purchase 50,000 shares of common stock at an exercise price of \$2.70 per share at any time from December 27, 2006 until December 27, 2011, for investor relations consulting services rendered in 2007. All of the warrants are exercisable.
- j) In connection with offering of common stock in 2004, warrants to purchase a total of 120,756 shares of common stock were issued. All of the warrants are exercisable and expire five years from date of issuance.
- k) During 2002, a director who is also a scientific advisor received warrants to purchase 2,000 shares of common stock at an exercise price of \$24.55 per share at any time until February 1, 2009, for scientific consulting services rendered in 2002.

### 2001 Restricted Stock Plan

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

# **NOTE 10 - STOCK OPTION PLANS**

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

#### 2005 Equity Incentive Plan

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

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

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

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

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

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

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

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

#### 2007 Special Stock Option Plan

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

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

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

#### 1995 Stock Awards Plan

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

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

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

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

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

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

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

## NOTE 11 - SOMANTA ACQUISITION

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

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

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

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

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

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

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

	_	Twelve month December		
		2008	2007	
Net loss allocable to common stockholders	\$	(20,573) \$	(33,902)	
Net loss per common shares (basic and diluted)	\$	(3.51) \$	(6.71)	
Weighted average common shares outstanding (basic and diluted)		5,854	5,052	
	F-21			

# NOTE 12 - INCOME TAXES

Income tax expense differs from the statutory amounts as follows:

 2008	2007
\$ (6,995,000) \$	(7,393,000)
2,155,000	3,015,000
-	-
59,000	56,000
4,224,000	3,957,000
 557,000	365,000
\$ \$	
\$\$	\$ (6,995,000) \$ 2,155,000 59,000 4,224,000

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

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

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

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

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

# NOTE 13 – QUARTERLY FINANCIAL DATA (UNAUDITED)

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

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

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

# NOTE 14 – SUBSEQUENT EVENTS (UNAUDITED)

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

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



# Condensed Consolidated Balance Sheets

ASSETS	June 30, 2009 (unaudited)	December 31, 2008 (unaudited) (See Note 4)			
Current assets Cash and cash equivalents Receivables Prepaid expenses and other current assets	\$ 1,231,000 15,000 56,000	\$ 2,677,000 147,000 173,000			
Total current assets Property and equipment, net	<u> </u>	2,997,000			
Patents, net Other assets	70,000 909,000 70,000	1,015,000 123.000			
Total assets LIABILITIES AND STOCKHOLDERS' DEFICIT	\$ 2,351,000	\$ 4,230,000			
Current liabilities Accounts payable Accrued expenses Dividends payable Accrued interest payable Accrued interest payable Notes payable Current portion of deferred revenue Total current liabilities Long-term deferred revenue Long-term debt Total liabilities Commitments and contingencies Stockholders' deficit Convertible Series A preferred stock - \$.01 par value; authorized	\$ 3,653,000 1,029,000 1,866,000 340,000 256,000 7,144,000 3,533,000 5,500,000 16,177,000	\$ 3,824,000 798,000 1,896,000 145,000 825,000 164,000 7,652,000 2,245,000 5,500,000 15,397,000			
2,000,000 shares; 3,207.8617 issued at June 30, 2009 and 3,242.8617 at December 31, 2008 Common stock - \$.01 par value; authorized 100,000,000 shares; issued, 11,613,605 at June 30, 2009 and 9,467,474 at December 31, 2008 Additional paid-in capital Notes receivable from stockholders Treasury stock, at cost – 163 shares Accumulated deficit Total stockholders' deficit Total liabilities and stockholders' deficit	$\begin{array}{c} 116,000\\ 228,333,000\\ (1,045,000)\\ (4,000)\\ (241,226,000)\\ (13,826,000)\\ \hline \$ 2,351,000 \end{array}$	95,000 225,753,000 (1,045,000) (4,000) (235,966,000) (11,167,000) \$ 4,230,000			

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

# Condensed Consolidated Statements of Operations (unaudited)

	Three months ended June 30,			Six months ended June 30,					
	2009			2008		2009		2008	
				(See Note 4)		(See Note 4)	(	See Note 4)	
Revenues	¢	(2,000	¢	22 000	¢	104.000	¢	20.000	
License revenues	\$	63,000	\$	22,000	\$	104,000	\$	39,000	
Sponsored research and development		-		110,000		-		131,000	
Total revenues		63,000		132,000		104,000		170,000	
Expenses									
Research and development		582,000		10,855,000		1,269,000		21,012,000	
General and administrative		1,507,000		2,279,000		2,754,000		4,118,000	
Depreciation and amortization		66,000		78,000		132,000		166,000	
Total expenses		2,155,000	_	13,212,000	_	4,155,000		25,296,000	
Loss from operations		(2,092,000)		(13,080,000)		(4,051,000)		(25,126,000)	
Interest and miscellaneous income		2,000		40,000		16,000		141,000	
Interest and other expense		(118,000)		(221,000)		(262,000)		(329,000)	
		(116,000)		(181,000)		(246,000)		(188,000)	
Net loss		(2,208,000)		(13,261,000)		(4,297,000)		(25,314,000)	
Less preferred stock dividends		483,000		517,000		963,000		2,350,000	
Net loss allocable to common stockholders	\$	(2,691,000)	\$	(13,778,000)	\$	(5,260,000)	\$	(27,664,000)	
Basic and diluted loss per common share Net loss allocable to common shareholders	\$	(0.24)	\$	(1.69)	\$	(0.48)	\$	(3.45)	
Weighted average basic and diluted common shares outstanding		11,406,700		8,135,869		10,954,472		8,008,064	

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

# Condensed Consolidated Statement of Stockholders' Deficit (unaudited)

	Common	Stock	ock Preferred Stock					
	Shares	Amount	Shares	Amount	Additional paid-in capital	Notes receivable from stockholders	Treasury stock	Accumulated deficit
Access-MacroChem, as if combined at December 31, 2008 (See Note 4)	9,467,000	\$ 95,000	3,242.8617	\$ -	\$ 225,753,000	\$ (1,045,000)	\$ (4,000)	\$(235,966,000)
Common stock issued for preferred dividends	894,000	9.000	-	-	847,000	_	_	_
Warrants issued for	-	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	_	_	24,000	_	_	_
services Stock option compensation expense Common stock issued to MacroChem	-	-	-	-	56,000	-	-	-
noteholders for notes and accrued interest Common stock issued to	859,000	8,000	-	-	851,000	-	-	-
former MacroChem executives	95,000	1,000	-	-	132,000	-	-	-
Preferred dividends	-	-	-	-	-	-	-	(480,000) (2,089,000)
Net loss Balance at March 31, 2009	11,315,000	113,000	3,242.8617		227,663,000	(1,045,000)	(4,000)	(238,535,000)
Warrants issued for services	-	-	-	-	27,000	-	-	-
Stock option compensation expense Preferred stock	-	-	-	-	252,000	-	-	-
converted into common stock Common stock issued to	117,000	1,000	(35.0000)	-	(1,000)	-	-	-
former MacroChem executives	30,000	-	-	-	64,000	-	-	-
Common stock issued for cash exercise of options	25,000	-	-	-	14,000	-	-	-
Restricted common stock issued for services	127,000	2,000	-	-	314,000	-	-	-
Preferred dividends	-	-	-	-	-	-	-	(483,000)
Net loss Balance at June 30, 2009	- 11,614,000	- \$ 116,000	3,207.8617	- \$ -	\$ 228,333,000	<u>\$ (1,045,000)</u>	<u>-</u> <u>\$ (4,000)</u>	(2,208,000) \$(241,226,000)

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

# Access Pharmaceuticals, Inc. and Subsidiaries

# Condensed Consolidated Statements of Cash Flows (unaudited)

(unaudited)				
		ix Months ende		une 30, 008
Cash flows from operating activities:			_	
Net loss	\$	(4,297,000)	\$	(25,314,000)
Adjustments to reconcile net loss to cash used				
in operating activities:				
Depreciation and amortization		132,000		166,000
Stock option expense		308,000		673,000
Stock and warrants issued for services		564,000		100,000
Acquired in-process research and development		-		18,536,000
Change in operating assets and liabilities:		100 000		
Receivables		132,000		(70,000)
Prepaid expenses and other current assets		117,000		(255,000)
Other assets		53,000		-
Accounts payable and accrued expenses		60,000		(754,000)
Dividends payable		(137,000)		(25,000)
Accrued interest payable		229,000		209,000
Deferred revenue		1,380,000		1,069,000
Net cash used in operating activities		(1,459,000)		(5,665,000)
Cash flows from investing activities:				
Capital expenditures		(2,000)		(31,000)
Proceeds from sale of asset		1,000		-
Redemptions of short-term investments and certificate				1 470 000
of deposits		-		1,470,000
Virium acquisition by MacroChem, net of cash acquired		-		(240,000)
Somanta acquisition, net of cash acquired		- (1.000)		(65,000)
Net cash provided by (used in) investing activities		(1,000)		1,134,000
Cash flows from financing activities:				
Proceeds from debt issuance		-		400,000
Payments of notes payable		-		(639,000)
Proceeds from exercise of common stock options		14,000		15,000
Proceeds from preferred stock issuances, net of costs		-		2,444,000
Net cash provided by financing activities		14,000		2,220,000
Net deserves in each and each envirolants		(1,446,000)		(2,311,000)
Net decrease in cash and cash equivalents		2,677,000		2,582,000
Cash and cash equivalents at beginning of period	¢		¢	
Cash and cash equivalents at end of period	\$	1,231,000	\$	271,000
Supplemental cash flow information:				
Cash paid for interest	\$	-	\$	8,000
Sumlamental disclosure of non-cash turna actions.				
Supplemental disclosure of noncash transactions:		850 000		1 576 000
Shares issued for payables, notes payable and accrued interest		859,000 856,000		1,576,000
Shares issued for dividends on preferred stock				525 000
Preferred stock dividends in dividends payable Beneficial conversion feature –		963,000		525,000
February 2008 preferred stock dividends		-		857,000
November 2007 preferred stock dividends correction		-		451,000
Preferred stock issuance costs paid in cash		-		281,000
Debt discount related to MacroChem convertible debt issuance		-		93,000

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 June 30, 2009 and 2008 (unaudited)

#### (1) Interim Financial Statements

The consolidated balance sheet as of June 30, 2009, and the consolidated statements of operations and cash flows for the three and six months ended June 30, 2009, and 2008, 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, 2008. The results of operations for the period ended June 30, 2009, are not necessarily indicative of the operating results which may be expected for a full year. The consolidated balance sheet as of December 31, 2008, contains financial information taken from the audited Access financial statements as of that date and is combined with the unaudited financial data from MacroChem, as discussed further in Note 4.

The report of our independent registered public accounting firm for the fiscal year ended December 31, 2008, contained a fourth explanatory paragraph to reflect its significant doubt about our ability to continue as a going concern as a result of our history of losses and our liquidity position, as discussed herein and in this Form 10-Q. We expect that our capital resources and expected receipts due under our license agreements will be adequate to fund our current level of operations into the first quarter of 2010. 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.

On February 25, 2009, we closed our acquisition of MacroChem Corporation through the issuance of an aggregate of approximately 2.5 million shares of our common stock. Prior to our acquisition of MacroChem, SCO, an investment company, held a majority of Access' and MacroChem's voting stock. Specifically, SCO owned 53% of the voting stock of Access and 63% of the voting stock of MacroChem. A non-controlling interest of 37% existed at the merger date of MacroChem. In addition, certain members of SCO's management serve on the board of directors of both Access and MacroChem. Based on these facts, Access and MacroChem were deemed under the common control of SCO. As the entities were deemed under common control, the acquisition was recorded using the pooling-of-interest method and the financial information for all periods presented reflects the financial statements of the combined companies in accordance with Appendix D of Statement of Financial Accounting Standards No. 141R (SFAS 141R), "Business Combinations," for entities under common control. See also Note 4.

#### (2) Intangible Assets

Intangible assets consist of the following (in thousands):

	June 30, 2009					December 31, 2008				
	Gross carrying Accum			Gross mulated carrying tization value				Accumulated Amortization		
Amortizable intangible assets										
Patents	\$	2,624		\$	1,715	\$	2,624	\$1,609		
		F-29								

Amortization expense related to intangible assets totaled \$53,000 and \$106,000 for each of the three and six months ended June 30, 2009 and totaled \$53,000 and \$107,000 for each of the three and six months ended June 30, 2008. The aggregate estimated amortization expense for intangible assets remaining as of June 30, 2009 is as follows (in thousands):

2009	\$ 106
2010	212
2011	212
2012	82
2013	44
over 5 years	 253
Total	\$ 909

#### (3) Liquidity

The Company incurred significant losses allocable to common stockholders of \$5,260,000 for the six months ended June 30, 2009 and \$30,794,000 for the year ended December 31, 2008. At June 30, 2009, our working capital deficit was \$5,842,000. We expect that our capital resources and receipts due under our license agreements will be adequate to fund our current level of operations into the first quarter of 2010. However, our ability to fund operations over this time could change significantly depending upon changes to future operational funding obligations or capital expenditures. As a result we may be required to seek additional financing sources and enter into future licensing agreements for our products within the next twelve months.

After the quarter closed, we received \$1,000,000 in license receipts from an existing license agreement. Our cash balance at August 12, 2009 was \$1,553,000.

#### (4) MacroChem Acquisition

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

Prior to our acquisition of MacroChem, SCO, an investment company, held a majority of Access' and MacroChem's voting stock. Specifically, SCO owned 53% of the voting stock of Access and 63% of the voting stock of MacroChem. A non-controlling interest of 37% existed at the merger date of MacroChem. In addition, certain members of SCO's management serve on the board of directors of both Access and MacroChem. Based on these facts, Access and MacroChem were deemed under the common control of SCO. As the entities were deemed under common control, the acquisition was recorded using the pooling-of-interest method and the financial information for all periods presented reflects the financial statements of the combined companies in accordance with Appendix D of Statement of Financial Accounting Standards No. 141R (SFAS 141R), "Business Combinations," for entities under common control.



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

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

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

The income statement for all periods presented reflects the combined carrying amount of revenue and expenses. Below is a reconciliation of summary financial data for the period ended June 30, 2009 and the combined MacroChem financial data for the six months ended June 30, 2008 and the twelve months ended December 31, 2008. The balance sheet as of December 31, 2008 also reflects the combined entities.

Following is a summary balance sheet at December 31, 2008:

	Access Pharmaceuticals	MacroChem Corporation	Combined
Current assets Total assets	\$ 3,550,000 4,257,000	\$ 82,000 608,000	\$ 2,997,000 4,230,000
Current liabilities	4,906,000 2,245,000	3,485,000 29,000	7,652,000
Long-term deferred revenue Long-term debt	5,500,000	-	5,500,000
Stockholders' deficit	(8,394,000)	(2,906,000)	(11,167,000)

Intercompany receivables/payables of \$635,000 and intercompany deferred revenue of \$29,000 were eliminated.

Following is a summary statement of operations for the six months ended June 30, 2009 and June 30, 2008 and for the year ended December 31, 2008:

		For the six me	 	30	, 2009	For the year ended December 31, 2008				
	Pha	Access rmaceuticals	acroChem orporation		Combined	Access Pharmaceuticals	MacroChem Corporation	Combined		
Total revenues	\$	103,000	\$ 1,000	\$	104,000	\$ 291,000	\$ 4,000	\$ 295,000		
Expenses										
Research and development		1,269,000	-		1,269,000	12,613,000	10,698,000	23,311,000		
General and administrative Depreciation and		2,558,000	196,000		2,754,000	4,340,000	3,044,000	7,384,000		
amortization		105,000	 27,000		132,000	253,000	55,000	308,000		
Total expenses		3,932,000	 223,000		4,155,000	17,206,000	13,797,000	31,003,000		
Loss from operations		(3,829,000)	(222,000)		(4,051,000)	(16,915,000)	(13,793,000)	(30,708,000)		
Interest and miscellaneous income		16,000	-		16,000	178,000	33,000	211,000		
Interest and other expense Gain on change in value of		(236,000)	(26,000)		(262,000)	(478,000)	(433,000)	(911,000)		
warrant liability		-	 -		-		3,972,000	3,972,000		
2		(220,000)	 (26,000)		(246,000)	(300,000)	3,572,000	3,272,000		
Loss from operations		(4,049,000)	(248,000)		(4,297,000)	(17,215,000)	(10,221,000)	(27,436,000)		
Less preferred stock dividends		(963,000)	-		(963,000)	(3,358,000)	-	(3,358,000)		
Net loss allocable to common stockholders	\$	(5,012,000)	\$ (248,000)	\$	(5,260,000)	\$ (20,573,000)	\$ (10,221,000)	\$ (30,794,000)		
Basic and diluted loss per common share										
Net loss allocable to common stockholders Weighted average basic		-	-	\$	(0.48)	-	-	\$ (3.69)		
and diluted common shares outstanding		-	-		10,954,472	-	-	8,354,031		
			F-31							

		For the three m Access			
Total revenues	<u>Pha</u> \$	armaceuticals 132,000	<u>Corporation</u> \$ -	\$	Combined 132,000
Expenses Research and development General and administrative Depreciation and amortization		1,179,000 1,044,000 64,000	9,676,000 1,234,000 14,000		10,855,000 2,279,000 78,000
Total expenses Loss from operations		2,287,000 (2,155,000)	10,925,000 (10,925,000)	_	13,212,000 (13,080,000)
Interest and miscellaneous income Interest and other expense		29,000 (117,000)	11,000 (104,000)		40,000 (221,000)
Loss from operations Less preferred stock dividends Net loss allocable to		(88,000) (2,243,000) (517,000)	(93,000) (11,018,000)	_	$(181,000) \\ (13,261,000) \\ (517,000) \\ (12,770,00$
common stockholders Basic and diluted loss per common share Net loss allocable to	2	(2,760,000)	<u>\$ (11,018,000)</u>	\$ \$	(13,778,000)
common stockholders Weighted average basic and diluted common shares outstanding		-	-	φ	(1.69) 8,135,869

## (5) Stock Based Compensation

For the three and six months ended June 30, 2009 we recognized stock-based compensation expense of \$252,000 and \$308,000. For the three and six months ended June 30, 2008 we recognized stock-based compensation expense of \$503,000 and \$673,000.

The following table summarizes stock-based compensation for the three and six months ended June 30, 2009, and 2008:

	Three months ended June 30,				Six months ended June 30,				
		2009		2008		2009		2008	
Research and development	\$	99,000	\$	26,000	\$	135,000	\$	39,000	
General and administrative		153,000		477,000		173,000		634,000	
Stock-based compensation expense included in operating expense	\$	252,000	\$	503,000	\$	308,000	\$	673,000	

We granted 475,000 stock options during the second quarter of 2009 and granted no stock options in the same period of 2008. MacroChem options were cancelled upon acquisition by Access and are no longer outstanding.

Our weighted average Black-Scholes fair value assumptions used to value the 2009 and 2008 first six months grants are as follows:

	6/30/09		6/30/08	
Expected life	5.5 yrs		6.2 yrs	
Risk free interest rate	2.4	%	3.0	%
Expected volatility <sup>(a)</sup>	114	%	133	%
Expected dividend yield	0.0	%	0.0	%

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

#### (6) Related Parties

David P. Luci, one of our directors, was also the President & Chief Business Officer of MacroChem, with which we acquired on February 25, 2009 pursuant to the Merger Agreement dated July 9, 2008. We signed an amended Consulting, Settlement and Release Agreement with Mr. Luci on March 16, 2009 where he received 60,000 shares of our restricted common stock and \$27,500 in a one time cash payment to settle his rights under a previous consulting agreement with MacroChem. On June 1, 2009 we signed a consulting agreement with Mr. Luci where Mr. Luci will provide consulting services to Access for cash compensation of \$9,415 per month and for 200,000 shares of our restricted common stock and a cash bonus if certain events occur, as defined in the agreement. The restricted common stock vests 66,667 shares on June 1, 2009, 66,666 shares on January 1, 2010 and 66,667 shares on June 1, 2010.

#### (7) Fair Value of Financial Instruments

SFAS 107-1, *Interim Disclosure About Fair Value of Financial Instruments,* requires disclosure about the fair value of all financial assets and liabilities for which it is practicable to estimate. 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.

#### (8) Subsequent Events

In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through August 12, 2009, the date the financial statements were issued.

## INDEX

## Page No.

Report of Independent Public Accounting Firm	F-35
Consolidated Balance Sheet at December 31, 2008	F-36
Consolidated Statement of Operations for Year Ended December 31, 2008	F-37
Consolidated Statement of Stockholders' Deficit for Year Ended December 31, 2008	F-38
Consolidated Statement of Cash Flows Year ended December 31, 2008	F-39
Notes to Consolidated Financial Statements	F-40

#### **REPORT OF INDEPENDENT AUDITORS**

To the Board of Directors and Stockholders of MacroChem Corporation

We have audited the accompanying consolidated balance sheet of MacroChem Corporation and subsidiary (the "Company") as of December 31, 2008 and the related consolidated statements of operations, stockholders' deficit and cash flows for the year then ended. These consolidated 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 audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. 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, nor have we been 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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 MacroChem Corporation and subsidiary as of December 31, 2008, and the results of their operations and their cash flows for the year 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 1 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 1. 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 August 25, 2009

## CONSOLIDATED BALANCE SHEET

ASSETS	December 31, 2008
Current assets Cash and cash equivalents Prepaid expenses and other current assets Total current assets	\$ 14,000 70,000 84,000
Property and equipment, net	8,000
Patents, net Total assets LIABILITIES AND STOCKHOLDERS' DEFICIT	<u>457,000</u> <u>\$ 549,000</u>
Current liabilities Accounts payable Accrued expenses and other liabilities Accrued interest payable Current portion of deferred revenue Note payable – Access Pharmaceuticals, Inc. Note payable – related party Notes payable Total current liabilities	\$ 1,317,000 547,000 17,000 5,000 635,000 225,000 600,000 3,346,000
Long-term deferred revenue Warrants liability Total liabilities	<u> </u>
Commitments and contingencies	
Stockholders' deficit Common stock - \$.01 par value; authorized 100,000,000 shares; 45,873,412 issued at December 31, 2008; 22,500,026 issued at December 31, 2007 Additional paid-in capital Treasury stock, at cost – 529 shares Accumulated deficit Total stockholders' deficit Total liabilities and stockholders' deficit	459,000 97,763,000 (59,000) (101,088,000) (2,925,000) \$ 549,000

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

## CONSOLIDATED STATEMENT OF OPERATIONS

	Year Ended December 31, 2008
Revenues:	
License revenues	\$ 4,000
Total revenues	4,000
Expenses:	
Research and development	10,622,000
General and administrative	3,123,000
Depreciation and amortization	71,000
Total expenses	13,816,000
Loss from operations	(13,812,000)
Interest and other income	26,000
Interest and other expense	(433,000)
Gain on change in value of warrants liability	3,972,000
Gain on sale of equipment	7,000
	3,572,000
Net loss	\$(10,240,000)
Basic and diluted loss per common share	\$ (0.26)
Weighted average basic and diluted common shares	
outstanding	38,934,207

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

## CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIT For the year ended December 31, 2008

	Common Sto	ck Shares									
	Issued	Treasury	-	ommon Stock	Additional Paid-In Capital		Accumulated Deficit	Treasury Stock, at cost		St	Total tockholders' Deficit
Balance,		(500)	<i>•</i>	<b></b>	<b>^</b>	~~~~	<b>*</b> ( <b>* * * * * * * * * *</b>	<i><b></b></i>		<i>•</i>	
December 31, 2007	22,500,026	(529)	\$	225,000	\$	90,054,000	\$ (90,848,000)	\$	(59,000)	\$	(628,000)
Common stock and warrants issued to Virium											
shareholders	22,898,386	-		229,000		6,788,000	-		-		7,017,000
Common stock											
issued for services	400,000	-		4,000		116,000	-		-		120,000
Warrants issued with debt						75,000					75,000
Warrants issued for	-	-		-		75,000	-		-		75,000
services	-	-		-		36,000	-		-		36,000
Convertible notes beneficial						,					
conversion feature	_	-		-		188,000	_		_		188,000
Stock-based compensation						100,000					100,000
expense	75,000	-		1,000		506,000	-		-		507,000
Net loss	-	-		-		-	(10,240,000)		-		(10,240,000)
Balance,							<u> </u>				<u>, , , , ,</u> ,
December 31, 2008	45,873,412	(529)	\$	459,000	\$	97,763,000	\$(101,088,000)	\$	(59,000)	\$	(2,925,000)

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

## CONSOLIDATED STATEMENT OF CASH FLOWS

	Year ended December 31, 2008	
Cash flows from operating activities:		
Net loss	\$	(10,240,000)
Adjustments to reconcile net loss to net cash used		
in operating activities:		
Stock based compensation expense		507,000
Stock and warrants issued for services		156,000
Acquired in-process research and development		9,661,000
Depreciation and amortization		71,000
Amortization of debt discount and beneficial conversion feature		263,000
Gain on change in value of warrants liability		(3,972,000)
Gain on sale of equipment		(7,000)
Change in operating assets and liabilities:		
Prepaid expenses and other current assets		61,000
Accounts payable and accrued expenses		84,000
Accrued interest payable		17,000
Net cash used in operating activities		(3,399,000)
Cash flows from investing activities:		
Sales of short-term investments		759,000
Expenditures for property and equipment		(3,000)
Proceeds from sale of asset		13,000
Payments for acquisition of Virium, net of cash acquired		(240,000)
Net cash provided by investing activities		529,000
Cash flows from financing activities:		
Proceeds from debt issuance		400,000
Proceeds from note payable – Access Pharmaceuticals, Inc.		635,000
Repayment of debt		(575,000)
Net cash provided by financing activities		460,000
Net decrease in cash and cash equivalents		(2,410,000)
Cash and cash equivalents at beginning of year		2,424,000
Cash and cash equivalents at end of year	\$	14,000
Supplemental cash flow information: Cash paid for interest	\$	133,000

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

#### MACROCHEM CORPORATION AND SUBSIDIARY NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Nature of Business and Summary of Significant Accounting Policies.

MacroChem Corporation (the "Company") is a specialty pharmaceutical company that develops and seeks to commercialize pharmaceutical products using its proprietary drug delivery technologies.

The Company has been engaged primarily in research and development since its inception in 1981 and has derived limited revenues from the commercial sale of its products, licensing of certain technology and feasibility studies. The Company has had minimal revenues relating to the sale of any products currently under development. The Company has incurred losses from operations every year since its inception and the Company anticipates that operating losses may continue for the foreseeable future. At December 31, 2008 the Company's accumulated deficit was approximately \$101.1 million. The audit report of Whitley Penn LLP, our independent public accounting firm on our 2008 financial statements includes an explanatory paragraph concerning our ability to continue as a going concern. The inclusion of this explanatory paragraph may materially and adversely affect our ability to raise new capital. To continue to operate, the Company will require significant additional funding. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company was acquired by Access Pharmaceuticals, Inc. ("Access") on February 25, 2009 per the agreement and plan of merger entered into on July 10, 2008. The impact of this transaction is not reflected in these consolidated financial statements. See Note 11.

The Company organizes itself as one segment reporting to the chief executive officer. Products and services consist primarily of research and development activities in the pharmaceutical industry.

<u>Principles of Consolidation</u> - The consolidated financial statements include the financial statements of MacroChem Corporation and our wholly-owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

<u>Accounting Estimates</u> – The preparation of the 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 amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. The primary estimates underlying the Company's consolidated financial statements include the fair market value of warrants included in liabilities, the carrying value and useful lives of the Company's patents and property and equipment, the valuation allowance established for the Company's deferred tax assets, and the underlying assumptions to apply the pricing model to value stock options under Statement of Financial Accounting Standards ("SFAS") No. 123 (revised 2004), "*Share-Based Payment*,". Management bases its estimates on certain assumptions, which it believes are reasonable in the circumstances, and while actual results could differ from those estimates, management does not believe that any change in those assumptions in the near term would have a significant effect on the consolidated financial position or the results of operations.

Fair Value of Financial Instruments – The carrying amounts of cash, cash equivalents, accounts payable, notes payable and accrued expenses approximate their fair value because of their short-term nature.

<u>Cash and Cash Equivalents</u> – Cash and cash equivalents at December 31, 2008 are primarily comprised of highly liquid investments with a maturity of three months or less when purchased. There were no short-term investments at December 31, 2008. During the year we maintained deposits primarily in one financial institution, which may at times exceed amounts covered by insurance provided by the U.S. Federal Deposit Insurance Corporation ("FDIC"). We have not experienced any losses related to amounts in excess of FDIC limits.

<u>Property and Equipment</u> – Property and equipment are stated at cost. Depreciation and amortization are provided on the straight-line method over the estimated useful lives of the related assets, which range from three to ten years.

Patents – The Company has filed applications for United States and foreign patents covering aspects of its technology. Costs and expenses incurred in connection with pending patent applications are deferred. Costs related to successful patent applications are amortized over the estimated useful lives of the patents, not exceeding 20 years, using the straight-line method. Accumulated patent costs and deferred patent application costs related to patents that are considered to have limited future value are charged to expense. Accumulated amortization aggregated approximately \$487,000 at December 31, 2008. On an on-going basis, the Company evaluates the recoverability of the net carrying value of various patents by reference to the patent's expected use in drug and other research activities as measured by outside interest in the Company's patented technologies and management's determination of potential future uses of such technologies. At December 31, 2008:

Gross carrying value	\$ 944,000
Accumulated amortization	(487,000)
Net asset value	\$ 457,000

The aggregate estimated amortization expense for intangible assets remaining as of December 31, 2008 is as follows (in thousands):

2009	\$ 45
2010	45
2011	45
2012	45
2013 and thereafter	277
Total	\$ 457

For the year ended December 31, 2008, amortization expense was \$61,000.

<u>Long-lived Assets</u> – The Company reviews its long-lived assets for impairment when events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable. Recoverability of such assets to be held and used is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. No impairment charges were recorded for the year ended December 31, 2008.

<u>Research and Development</u> – Research and development costs are charged to operations as incurred. Such costs include proprietary research and development activities and expenses associated with research and development contracts, whether performed by the Company or contracted with independent third parties. Research and development also includes in-process research and development of \$9,661,000 from the acquisition of Virium in 2008.

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

#### Stock Based Compensation - Adoption of SFAS 123(R)

Prior to January 1, 2006, the Company accounted for stock-based compensation issued to employees using the intrinsic value method, which follows the recognition and measurement principles of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," and Financial Accounting Standards Board ("FASB") Interpretation ("FIN") No. 44, "Accounting for Certain Transactions Involving Stock Compensation."

Generally, no stock-based employee compensation cost related to stock options was reflected in net income, as all options granted under stockbased compensation plans had an exercise price equal to the market value of the underlying common stock on the grant date. Compensation cost related to restricted stock units granted to non-employee directors and certain key employees was reflected as an expense as services were rendered.

On January 1, 2006, the Company adopted SFAS No. 123(R), "Share-Based Payment," using the modified prospective method, which requires measurement of compensation cost for all stock awards at fair value on the date of grant and recognition of compensation over the requisite service period for awards expected to vest. The fair value of stock options is estimated using the Black-Scholes valuation model, and the fair value of restricted stock units is determined based on the number of shares granted and the quoted price of the Company's common stock on the date of grant. Such value is recognized as expense over the requisite service period, net of estimated forfeitures, using the straight-line attribution method. The estimate of awards that will ultimately vest requires significant judgment, and to the extent actual results or updated estimates differ from the Company's current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. The Company considers many factors when estimating expected forfeitures, including types of awards, employee class and historical employee attrition rates. Actual results, and future changes in estimates, may differ substantially from the Company's current estimates.

Stock based compensation expense for the year ended December 31, 2008 is as follows:

	Year Ended December 31, 2008	
General and administrative	\$	507,000

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

As of January 1, 2007, we adopted FASB Interpretation No. 48, "*Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109, Accounting for Income Taxes*" ("FIN 48"). The adoption did not have a material impact on our consolidated financial statements or effective tax rate and did not result in any unrecognized tax benefits. Interest costs and penalties related to income taxes are classified as interest expense and general and administrative costs, respectively, in our consolidated financial statements. For the year ended December 31, 2008, 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 subsidiary file income tax returns in the U.S. federal jurisdiction.

<u>Basic and Diluted (Loss) Income Per Share</u> – Basic earnings per share is computed using the weighted average number of common shares outstanding during each year. For the year ended December 31, 2008, potential common shares are not included in the per share calculations for diluted EPS, because the effect of their inclusion would be anti-dilutive. Anti-dilutive potential shares from stock options, warrants and convertible debt not included in per share calculations under the treasury stock method for 2008 were 25,768,998.

Basic and Diluted Income (Loss) Per Share		Year Ended December 31, 2008	
Basic net (loss) income attributable to common stockholders	\$	(10,240,000)	
Basic and diluted net (loss) income per common share	\$	(0.26)	
Weighted average shares used to compute basic and dilut	ed		
net (loss) income per common share		38,934,207	

<u>Recent Accounting Pronouncement</u>– In September 2006, the FASB issued SFAS No. 157, "*Fair Value Measurements*" ("SFAS 157"). SFAS 157 defines fair value, establishes a market-based framework or hierarchy for measuring fair value, and expands disclosures about fair value measurements. SFAS 157 is applicable whenever another accounting pronouncement requires or permits assets and liabilities to be measured at fair value. SFAS 157 does not expand or require any new fair value measures; however the application of this statement may change current practice. The requirements of SFAS 157 became effective for our fiscal year 2008. However, in February 2008 the FASB decided that an entity need not apply this standard to nonfinancial assets and liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis until the subsequent year. Accordingly, our adoption of this standard on January 1, 2008 was limited to financial assets and liabilities and did not have a material effect on our financial condition or results of operations. The financial assets and liabilities as reported in the Company's financial statements approximate their respective fair value. The Company's warrant liability is included in level 2 of the fair value hierarchy contained in SFAS 157. We are still in the process of evaluating this standard with respect to its effect on nonfinancial assets and liabilities and therefore have not yet determined the impact that it will have on our financial statements upon full adoption.

In February 2007, the FASB issued SFAS No. 159, *"The Fair Value Option for Financial Assets and Financial Liabilities* — including an amendment of FASB 115" ("SFAS 159") which allows an entity to choose to measure certain financial instruments and liabilities at fair value. Subsequent measurements for the financial instruments and liabilities an entity elects to fair value will be recognized in earnings and this election is irrevocable. SFAS 159 also establishes additional disclosure requirements. SFAS 159 is effective for the Company beginning January 1, 2008. The Company has not elected to apply the fair value option to any of its financial instruments.

In December 2007, the FASB issued SFAS No.141 (revised 2007), "Business Combinations" ("SFAS 141R"). SFAS 141R establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non controlling interest in the acquiree and the goodwill acquired. SFAS 141R also establishes disclosure requirements to enable the evaluation of the nature and financial effects of the business combination. SFAS 141R is effective beginning January 1, 2009. The Company is currently evaluating the potential impact of the adoption of SFAS 141R on its financial position, results of operations or cash flows.

In December 2007, the FASB issued SFAS No.160, "Non Controlling Interests in Consolidated Financial Statements-an amendment of Accounting Research Bulletin No. 51" ("SFAS 160"). SFAS 160 establishes accounting and reporting standards for ownership interests in subsidiaries held by the parties other than parent, the amount of the consolidated net income attributable to the parent and to the non controlling interest, changes in parent's ownership interest, and the valuation of retained non controlling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes disclosure requirements that clearly identify and distinguish between the interests of the parent and interests of the non controlling owners. SFAS 160 is effective for the Company beginning January 1, 2009. The Company is currently evaluating the potential impact of the adoption of FAS 160 on its financial position, results of operations or cash flows.

In March 2008, the FASB issued SFAS No. 161 "Disclosures about Derivative Instruments and Hedging Activities-an amendment of FASB Statement No. 133" ("SFAS 161"). SFAS 161 enhances disclosures about the Company's derivative and hedging activities and thereby improves the transparency of financial reporting. SFAS 161 is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. The Company is currently evaluating the potential impact of the adoption of SFAS 161 on its financial position, results of operations or cash flows.

On October 10, 2008, the FASB issued FSP No. SFAS 157-3, "Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active." ("FSP SFAS 157-3") clarifies the application of SFAS No. 157, "Fair Value Measurements," in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. FSP SFAS 157-3 is effective immediately, including prior periods for which financial statements have not been issued. The adoption of FSP SFAS 157-3 did not have a material impact on the Company's consolidated financial statements.

#### 2. Property and Equipment.

Property and equipment consists of the following as of December 31:

	2008	
Office equipment	\$ 493,000	
Less: accumulated depreciation	(485,000)	
Property and equipment, net	\$ 8,000	

#### 3. Accrued Expenses and Other Liabilities.

Accrued expenses and other liabilities consists of accrued patent expenses of \$300,000 and other accrued expenses of \$247,000 as of December 31, 2008.

#### 4. Debt

On August 27, 2008, the Company entered into a Note Purchase Agreement with Access Pharmaceuticals, Inc., pursuant to which Access has loaned us in aggregate the amount of \$635,000 at December 31, 2008 and agreed to loan additional funds to us as required to operate our business until the date of termination of the agreement or until the merger transaction is completed. We have agreed to pay interest to Access at the rate of 10% per annum.

See also Note 8 – Virium Pharmaceuticals, Inc. Acquisition for details of the notes related to the acquisition. Of the \$825,000 outstanding at December 31, 2008, \$225,000 was held by SCO and related parties.

As described at Note 8, default status of one of these notes at December 31, 2008 resulted in a beneficial conversion feature with a value of \$188,000 recorded to interest expense and additional paid-in capital.

All of MacroChem's outstanding debt and accrued interest was cancelled in exchange for Access common stock upon acquisition, see Note 11.

#### 5. Stock-Based Compensation

<u>Stock Incentive Plans</u> – The Company has granted options to purchase the Company's common stock to employees and directors under various stock incentive plans. Under the plans, employees and non-employee directors are eligible to receive awards of various forms of equity-based incentive compensation, including stock options, restricted stock, and performance awards, among others. The plans are administered by the Board of Directors or the Compensation Committee of the Board of Directors, which determine the terms of the awards granted. Stock options are generally granted with an exercise price equal to the market value of a share of common stock on the date of grant, have a term of ten years or less, and vest over terms of two to three years from the date of grant.

Stock Option Plans – The Company has three stock option plans, the 1994 Equity Incentive Plan (the "1994 Plan") and the 2001 Incentive Plan (the "2001 Plan") and the 2008 Stock Incentive Plan (the "2008 Plan").

Under the terms of the 1994 Plan, the Company may no longer award any options. All options previously granted under the 1994 Plan may be exercised at any time up to ten years from the date of award.

Under the terms of the 2001 Plan, the Company may grant options to purchase up to a maximum of 2,373,809 shares of common stock to certain employees, directors and consultants. The options may be awarded as incentive stock options (employees only) and non-incentive stock options (certain employees, directors and consultants).

The 2008 Plan, 2001 Plan and the 1994 Plan state that the exercise price of options shall not be less than fair market value at the date of grant. As of December 31, 2008, there were outstanding options under all plans to purchase 4,126,232 shares of common stock with 4,373,768 shares remaining available for future grants under the 2001 and 2008 Plan.

<u>Stock-Based Compensation</u> Effective January 1, 2006, the Company adopted FAS No. 123(R), "Accounting for Stock-Based Compensation," ("FAS 123(R)") using the modified prospective method, which results in the provisions of FAS 123(R) being applied to the financial statements on a going-forward basis. FAS 123(R) requires companies to recognize stock-based compensation awards granted to its employees as compensation expense on a fair value method. Under the fair value recognition provisions of FAS 123(R), stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as expense over the service period, which generally represents the vesting period. The grant date fair value of stock options is calculated using the Black-Scholes option-pricing model and the grant date fair value of restricted stock is based on intrinsic value. The expense recognized over the service period is required to include an estimate of the awards that will be forfeited.

All stock-based awards to non-employees are accounted for at their fair market value in accordance with FAS 123(R) and Emerging Issues Task Force No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Under this method, the equity-based instrument was valued at either the fair value of the consideration received or the equity instrument issued on the date of grant. The resulting compensation cost was recognized and charged to operations over the service period, which was usually the vesting period.

For purposes of recording stock based compensation expense as required by Statement No. 123(R), the fair values of each stock option granted under the Company's stock option plan for the fiscal year ended December 31, 2008, was estimated as of the date of grant using the Black-Scholes option-pricing model.

The fair values of all 2008 stock option grants issued were determined using the following weighted average assumptions:

	Year Ended December 31, 2008
Risk-free interest rate	2.96 %
Expected life of option grants	6.0 years
Expected volatility of underlying stock	111 %
Expected dividend payment rate, as a percentage of the stock price on the date of grant	0 %

The dividend yield assumption is based on the Company's history and expectation of future dividend payouts. The Company estimated stock price volatility using the historical volatility in the market price of its common stock for the expected term of the options. The risk-free interest rate assumption is based upon the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option.

As share-based compensation expense is recognized based on awards ultimately expected to vest, it must be reduced for estimated forfeitures. FAS 123(R) requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeiture rates are calculated based on actual historical forfeitures. The Company assumed a 100% forfeiture rate for all unvested options at December 31, 2008 due to the acquisition by Access on February 25, 2009. See Note 11.

The expected term of the options represents the estimated period of time until exercise and is based on historical experience of similar awards. The expected life of employee stock options is, in part, a function of the options' remaining contractual life and the extent to which the option is in-the-money (i.e., the average stock price during the period is above the strike price of the stock option). We use the "simplified method" until we have enough historical experience to provide a reasonable estimate of expected term.

<u>Stock Option Activity</u>– During the year ended December 31, 2008, the Company granted stock options to existing employees and Directors, as part of the Company's yearly review process. All such options were granted with exercise prices equal to the current market value of the underlying common stock on the date of grant. Stock option activity was as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term
Balance, December 31, 2007	3,020,249 \$	3.90	
Granted	4,840,000	0.30	
Exercised			
Canceled	(3,734,017) \$	2.66	
Outstanding at, December 31, 2008	4,126,232 \$	0.58	8.92
Exercisable, December 31, 2008	1,939,417 \$	2.58	8.63

There was no intrinsic value of options at December 31, 2008.

The following table summarizes information relating to currently outstanding and exercisable options as of December 31, 2008 as follows:

Exercise Price	Number of Shares	Outstanding Weighted-Average Remaining Contractual Life (in Yrs)	Weighted Average Exercise Price	Exercisable Number of Shares	Weighted Average Exercise Price
\$0.24 - \$0.30 \$0.60 - \$1.62 \$10.50 - \$69.30	2,540,000 1,575,000 <u>11,232</u> 4,126,232	9.39 8.18 6.19	\$0.29 \$0.88 \$22.76	927,498 1,000,687 11,232 1,939,417	\$3.40 \$1.60 \$22.76

Stock based compensation expense for the year ended December 31, 2008 related to stock options was \$485,000. As of December 31, 2008, there was no expected unrecognized compensation cost related to unvested stock options granted under the Company's stock-based compensation plans as forfeitures were estimated at 100%.

All outstanding options at December 31, 2008 were canceled February 25, 2009 with the acquisition by Access Pharmaceuticals, Inc.

Stock and Stock Option Issuances to Non-Employees - During 2008, no stock options were granted to non-employees or consultants.

#### Restricted Stock Activity

On March 7, 2008, the Company issued 400,000 shares of common stock to a consultant to the Company for services to be performed in the first three quarters of 2008. The common shares vested immediately and were not subject to forfeiture. The common shares had a fair value of \$120,000 on the grant date.

#### Stock and Stock Option Issuances to Employees Outside the Stock Option Plans-

On April 22, 2008, the Company issued 75,000 shares of common stock to the Company's Chairman Robert DeLuccia. The common shares vested immediately and were not subject to forfeiture. The common shares had a fair value of \$22,500 and was recorded to stock-based compensation expense.

During 2006, 75,000 shares of restricted stock were granted to Robert J. DeLuccia, the Company's Chief Executive Officer. The restricted stock vests if and when the Company's common stock trades at or above \$4.00 per share for thirty consecutive trading days. None of these awards had vested as of December 31, 2008 and all were cancelled upon acquisition by Access in 2009.

#### 6. Stockholders' Equity.

#### Authorized Capital Stock

Authorized capital stock consists of 100,000,000 shares of \$.01 par value common stock of which 45,873,412 shares are issued (45,872,883 are outstanding) and 30,142,767 are reserved for issuance upon exercise of common stock options and warrants at December 31, 2008. Authorized preferred stock totals 6,000,000 shares, of which 500,000 shares have been designated Series A Preferred Stock, 600,000 shares have been designated Series B Preferred Stock and 1,500 shares have been designated Series C Cumulative Convertible Preferred Stock. On December 31, 2008, there were no shares of Series A, B or C Cumulative Preferred Stock outstanding.

#### Stock Sales

On October 10, 2007, the Company entered into a Securities Purchase Agreement, pursuant to which the Company issued in a private placement 5,891,667 shares of its common stock and five-year warrants to purchase 1,767,500 shares of the Company's common stock at an exercise price of \$0.60 per share, for aggregate gross proceeds of \$3,535,000. In connection with the private placement, all of the 752.25 then outstanding shares of the Company's Series C Cumulative Convertible Preferred Stock were converted into a total of 12,571,850 shares of common stock. In addition, outstanding warrants to purchase 8,648,102 shares of common stock previously issued with the Series C Preferred have been reset to purchase 17,885,848 shares of common stock at an exercise price of \$0.60 per share, pursuant to anti-dilution provisions of those warrants.

In connection with the private placement, the Company entered into a Director Designation Agreement dated as of October 1, 2007 with SCO Capital Partners, LLC ("SCO"), a current stockholder and a purchaser in the private placement, pursuant to which, for so long as SCO holds 20% of the Company's outstanding common stock, SCO has the right to designate two individuals to serve on the Company's Board of Directors. SCO previously held the right to designate two individuals to serve on the Company's Board of Directors for so long as it held 20% of the Company's outstanding Series C Preferred. SCO was paid \$150,000 in investor relations fees in 2008.

#### Warrants

As discussed at note 8, on June 23, 2008, the Company entered into a \$425,000 Convertible Note agreement with new holders of convertible promissory notes whose notes mature on December 12, 2008, subject to certain conditions. The note holders received warrants to purchase 212,500 shares of common stock at an exercise price of \$.01 per share for a period of five years. These warrants were valued at \$51,000 using the Black Scholes model and are being amortized over the term of the debt. As of December 31, 2008, none of the warrants had been exercised.

As discussed at Note 8, on June 23, 2008, the Company entered into a \$400,000 Convertible Note agreement with new holders of convertible promissory notes whose notes mature on December 6, 2008, subject to certain conditions. The note holders received warrants to purchase 100,000 shares of common stock at an exercise price of \$.01 per share for a period of five years. These warrants were valued at \$24,000 using the Black Scholes model and are being amortized over the term of the debt. As of December 31, 2008, none of the warrants had been exercised.

On March 5, 2008, the Company entered into an agreement with a consultant for consulting services, with the consultant receiving warrants to purchase 150,000 shares of common stock at an exercise price of \$0.38 for a period of five years. These warrants were valued at \$36,000 using the Black Scholes model. As of December 31, 2008, none of the warrants had been exercised.

On October 10, 2007, in connection with the conversion of its Series C Preferred Stock to shares of common stock, warrants to purchase 8,648,102 shares of common stock previously issued with the Series C Preferred Stock have been reset to purchase 17,885,847 shares with an exercise price of \$.60 per share pursuant to anti-dilution provisions in the warrants. On February 13, 2006, the Company closed a private placement in which institutional investors received six-year warrants to purchase 11,510,018 shares of the Company's common stock at an exercise price of \$0.60 per share ("Investor Warrants"). As of December 31, 2008, none of the \$0.60 Investor Warrants had been exercised. The placement agent in the transaction received a warrant to purchase approximately 959,166 shares of common stock at a purchase price of \$0.60 for a period of six years ("Placement Agent Warrants"). As of December 31, 2008, none of these \$0.60 Placement Agent Warrants had been exercised. On December 23, 2005, the Company closed a private placement in which institutional investors received warrants to purchase 4,999,997 shares of common stock at an exercise price of \$0.60 per share for a period of six years ("Investor Warrants"). As of December 31, 2008, 37,500 of these \$0.60 Investor Warrants had been exercised. The placement agent in this transaction received a warrant to purchase approximately 416,666 shares of common stock at a purchase price of \$0.60 for a period of six years ("Placement Agent Warrants"). As of December 31, 2008, none of the \$0.60 Placement Agent Warrants had been exercised. In accordance with EITF 00-19, "Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock" ("EITF 00-19"), the Investor Warrants and the Placement Agent Warrants are included as a liability and valued at fair market value until the Company meets the criteria under EITF 00-19 for permanent equity due to a put option in the agreement. Changes in the fair value of such warrants are recorded as a charge or credit to operations each reporting period. The Company valued the Investor Warrants and the Placement Agent Warrants at \$104,000 on December 31, 2008 using the Black-Scholes model with the following assumptions: a risk-free interest rate of 1.0%, volatility of 115%, expected life of 3 years and a dividend yield of 0%. The change in the value of the warrants liability from the prior year resulted in a gain of \$3,972,000.

On October 10, 2007, the Company closed a private placement in which institutional investors received warrants to purchase 1,767,500 shares of common stock for a period of five years. The exercise price of the warrants is \$0.60 per share. The placement agent also received warrants to purchase 589,166 shares of common stock for a period of five years. The exercise price of these warrants is \$0.60. At December 31, 2008, none of these warrants had been exercised.

On April 19, 2005, the Company closed a private placement in which institutional investors and certain executive officers and directors of the Company received warrants to purchase 32,520 shares of common stock for a period of five years. The exercise price of the warrants is \$14.70 per share for the institutional investors and \$21.84 for the participating executive officers and directors. As of December 31, 2008, 6,012 of the \$14.70 warrants issued to the institutional investors had been exercised and none of the \$21.84 warrants issued to participating executive officers and directors had been exercised. The placement agent in this transaction received a warrant to purchase 1,190 shares of common stock at a purchase price of \$14.70 for a period of five years. As of December 31, 2008, none of the \$14.70 warrants issued to the placement agent had been exercised.

During 2004, the Company conducted a private placement in which primarily institutional investors received warrants to purchase an aggregate of 25,723 shares of common stock at a purchase price of \$87.78 per share for a period of five years. As of December 31, 2008, none of the \$87.78 warrants had been exercised.

#### Shareholder Rights Plan

The Company has adopted a shareholder rights plan. The Company declared a dividend consisting of one Right for each share of common stock outstanding on September 10, 1999. Stock issued after that date will be issued with an attached Right.

Each Right entitles the holder, upon the occurrence of certain events, to purchase 42/100 <sup>th</sup> of a share of Series B Preferred Stock of the Company at an initial exercise price of \$2,100, subject to adjustments for stock dividends, splits and similar events. The Rights are exercisable only if a person or group acquires 20% or more of the Company's outstanding common stock, or announces an intention to commence a tender or exchange offer, the consummation of which would result in ownership by such person or group of 20% or more of the Company's outstanding common stock.

On December 23, 2005, the shareholder rights plan was amended to provide that the acquisition of the Company's Series C Cumulative Convertible Preferred Stock and warrants to acquire shares of its common stock by the purchasers in the Company's recent private placement, and any subsequent acquisition by the purchasers of common stock upon the conversion or exercise of those securities, would not result in the Rights becoming exercisable.

The Board of Directors may, at its option after the occurrence of one of the events described above, exchange all of the then outstanding and exercisable Rights for shares of common stock at an exchange ratio of one share of common stock per Right.

The Board of Directors may redeem the Rights at the redemption price of \$0.01 per Right at any time prior to the expiration of the rights plan on August 13, 2009. Distribution of the Rights is not a taxable event to shareholders.

#### 7. Commitments and Contingencies.

At December 31, 2008, the Company had no long-term contractual obligations.

#### RAI Merger

On April 17, 2008, the REIT Americas Inc. ("RAI") and Virium Pharmaceuticals agreed to terminate the Merger Agreement that had been entered into on May 25, 2007 by and among RAI and Virium Pharmaceuticals. Upon completion of a qualified financing, the Company will be obligated to pay RAI \$535,000 in consideration for agreeing to terminate the Merger Agreement.

#### 8. Virium Pharmaceuticals, Inc. Acquisition.

On April 18, 2008, the Company acquired Virium Pharmaceuticals Inc. ("Virium"), a privately held biotechnology company focused primarily on oncology based technology, pursuant to the terms of an Agreement and Plan of Merger (the "Merger Agreement") dated as of April 18, 2008 by and among the Company, VRM Acquisition, LLC, a Delaware limited liability company and a direct wholly-owned subsidiary of the Company ("VRM Acquisition"), Virium and Virium Holdings, Inc., a non-public Delaware corporation ("Holdings") and the parent of Virium. On the Effective Date, VRM Acquisition merged with and into Virium with Virium continuing as the surviving company and a wholly-owned subsidiary of the Company (the "Merger"). Pursuant to the Merger Agreement, each share of Virium common stock outstanding at the Effective Time was converted into the right to receive 0.89387756 shares of the Company's common stock (the "Merger Consideration") resulting in an aggregate of 22,898,386 shares of MacroChem common stock being issued in the Merger. The fair value of the shares issued on the closing date to the stockholders of Virium was \$6,870,000.

Virium has a pipeline of oncology products that target a variety of niche cancer indications. Virium's product pipeline included a next generation nucleoside analogue (small molecule) which it had licensed from the Southern Research Institute in August 2007. This class of compounds has demonstrated proven efficacy in certain hematological cancer indications. Upon completing the merger, management has commenced a process of conducting a strategic evaluation of each drug candidate in the Company's newly constituted product portfolio.

In addition, all outstanding warrants to purchase shares of Virium common stock were converted into warrants to purchase MacroChem common stock. After giving effect to the Merger, these vested warrants, which expire at various dates from 2012 to 2013, are exercisable to purchase 446,938 shares of MacroChem common stock at an exercise price of \$0.671 and 223,469 shares of MacroChem common stock at an exercise price of \$1.119 per share. As described in more detail below, MacroChem also assumed convertible notes of Virium.

On April 23, 2008, MacroChem assumed all obligations under the convertible promissory note in the aggregate principal amount of \$500,000 issued to Strategic Capital Resources, Inc. by Virium on May 30, 2007 (the "First Convertible Note"). The First Convertible Note was due to mature on April 25, 2008. The First Convertible Note had a 12% annual interest rate until November 30, 2007, which increased to 15% thereafter. MacroChem paid to Strategic Capital Resources, Inc. \$45,000 in cash which represents all accrued and unpaid interest on such note through the date of consummation of the Merger plus \$10,000. MacroChem made this payment in consideration of Strategic Capital Resources, Inc.'s prior agreement with Virium to extend the maturity date on its note from March 26, 2008 to April 25, 2008. Upon closing of MacroChem's next round of equity financing, if any, the principal amount of the First Convertible Note and all accrued interest may be converted into MacroChem common stock at the discretion of each First Convertible Note holder such that each holder will be entitled to acquire shares of MacroChem common stock at \$0.8950 per share, subject to anti-dilution adjustments.

On June 6, 2008, the Company repaid a principal amount of \$400,000 to the holder of the First Convertible Note together with accrued and unpaid interest thereon. Further, on June 23, 2008, the Company repaid the unpaid principal balance of \$100,000 together with accrued and unpaid interest thereon to the remaining holder of the First Convertible Note. Additionally, the First Convertible Note was repaid, in part, with funds from new holders of convertible promissory notes whose notes mature on December 6, 2008. The new promissory notes have a principal amount of \$400,000 and a warrant to purchase 100,000 shares of common stock at \$.01. The fair value of the warrants issued of \$24,000 is recorded as debt discount and is being amortized to interest expense over the term of the debt. The notes have a 12% interest rate with accrued interest due on or prior to the 5th day of each calendar month. These notes are due to mature on the earlier of 1) closing of the next financing by the Company or 2) December 6, 2008. The default status of these notes triggered the convertibility of 50% of the principal at a rate of \$0.018, which is 50% of the average market price for five days preceding the triggering event. This resulted in a beneficial conversion feature with a value of \$188,000 recorded to interest expense and additional paid-in capital. The principal amount of \$400,000 in notes was outstanding at December 31, 2008 and continued to accrue interest until February 25, 2009, the date of the acquisition by Access.

MacroChem also assumed on the Effective Date all obligations under convertible promissory notes in the aggregate principal amount of \$500,000 issued by Virium on December 12, 2007 (the "Second Convertible Notes"). The Second Convertible Notes were to mature on the earlier of (a) the closing of any equity financing by MacroChem or (b) June 12, 2008. The Second Convertible Notes have a 12% annual interest rate with all accrued interest due at maturity. Upon written consent to the borrower, simultaneously with the next round of financing, the holders have the ability to convert the entire outstanding principal and all accrued interest into shares. The conversion price will be equal to 50% of the qualified offering price.

In June 2008, a principal amount of \$425,000 of the Second Convertible Notes were extended to a maturity of December 31, 2008, subject to certain conditions and the Company repaid holders of the Second Convertible Notes a principal amount of \$75,000 and accrued interest of \$5,000. To induce the holders to extend the maturity, the Company issued 212,500 warrants to purchase common stock at \$.01. The fair value of the warrants issued of \$51,053 is recorded as debt discount and will be amortized to interest expense over the term of the debt. The principal amount of \$425,000 in notes was outstanding at December 31, 2008 and continued to accrue interest until February 25, 2009, the date of the acquisition by Access.

Prior to the merger agreement, SCO Capital Partners, LLC ("SCO LLC") together with its affiliates Beach Capital LLC, SCO Securities LLC and SCO Capital Partners, L.P. (collectively with SCO LLC, "SCO") was the owner of the outstanding common stock of MacroChem, including warrants to purchase certain shares, and also held a majority of the outstanding stock of Holdings and warrants to purchase 112,500 shares of Virium common stock. Pursuant to a Director Designation Agreement dated as of October 1, 2007 between MacroChem and SCO LLC, SCO LLC has the right to designate two individuals to serve on MacroChem's board of directors for so long as SCO holds 20% of MacroChem's outstanding common stock. The current SCO director designees are Jeffrey B. Davis and Mark J. Alvino. Mr. Davis is currently the president of SCO Securities LLC and Chief Executive Officer of Access Pharmaceuticals, Inc. Prior to the Effective Date, Mr. Davis was a director of Virium. Mr. Alvino is a former Managing Director of SCO Financial Group LLC and currently an officer of Griffin Securities, Inc. SCO Securities LLC acted as placement agent in connection with MacroChem's 2006 private placement.

Pursuant to the terms of the Merger Agreement, at the Effective Time, all members of the Special Committee, namely, John L. Zabriskie, Michael A. Davis, Paul S. Echenberg, and Peter G. Martin resigned from the board of directors of MacroChem.

Immediately following these resignations, David P. Luci and Dr. James Pachence were appointed to the board of directors of MacroChem. Dr. Pachence and Mr. Luci will be entitled to the standard compensation payable to our directors which as of April 22, 2008, is now applicable to all directors and includes compensation of \$12,000 annually, \$1,000 per regular board meeting attended, \$500 for each special, telephone or committee meeting attended and the stock option grants that our Compensation Committee from time to time deems appropriate. On June 26, 2008, Dr. James Pachence resigned from the office of Chief Executive Officer of the Company and resigned from his position as a member of our board of directors, in each case, effective immediately.

The acquisition of Virium on April 18, 2008 was accounted for by the Company under the purchase method of accounting in accordance with SFAS No. 141 "*Business Combinations*". Under the purchase method, assets acquired and liabilities assumed by the Company were recorded at their estimated fair values at the date of acquisition and the results of operations of the acquired company were consolidated with those of the Company from the date of acquisition. Virium is included in the Statement of Operations from the acquisition date on April 18, 2008.

The total purchase price of \$9,661,000, has been primarily allocated to be in-process research and development and is comprised of \$6,870,000 related to the calculated value of the Company's common stock issued of \$0.30 per share, \$2,404,000 of liabilities the Company assumed in addition to \$147,000 of warrants issued to certain debt holders. Additionally, the Company incurred \$240,000 in professional fees.

The components of the purchase price, which the Company has allocated to in-process research and development, are summarized as follows:

Common stock issued	\$ 6,870,000
Liabilities assumed	2,404,000
Warrants related to debt assumed	147,000
Transaction costs	 240,000
Total purchase price	\$ 9,661,000

The following unaudited pro forma information presents the 2008 results of the Company as if the acquisition had occurred on January 1, 2008. The unaudited pro forma results are not necessarily indicative of results that would have occurred had the acquisition been in effect for the periods presented, nor are they necessarily indicative of future results.

	2008 (unaudited)
Net income (loss)	\$ (10,564,000)
Net income (loss) per common share (basic and	
diluted) Weighted average common shares outstanding	\$ (0.23)
(basic and diluted)	45,754,492

#### 9. Income Taxes.

Income tax expense differs from the statutory amounts as follows:

	 2008
Income taxes at U.S. statutory rate Change in valuation allowance Expenses not deductible	\$ (3,482,000) 4,832,000 (1,350,000)
Total tax expense	\$ 

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

		<u>December 31,</u> 2008
Deferred tax assets		
Net operating loss carryforwards	\$	33,650,000
State credit		2,393,000
Intangible assets		383,000
Accrued interest		253,000
Deferred revenue		14,000
Other	-	231,000
Gross deferred tax assets		36,924,000
Valuation allowance	-	(36,924,000)
Net deferred taxes	\$_	_

No income tax provision or benefit has been provided for federal or state income tax purposes as the Company has incurred losses in all periods reported and recoverability of these losses in future tax filings is uncertain. As of December 31, 2008, the Company has available net operating loss carryforwards of approximately \$98,972,000 for federal income tax purposes, expiring through 2028 The use of the federal net operating loss may also be restricted due to changes in ownership in accordance with definitions as stated in the Internal Revenue Code.

As of January 1, 2007, we adopted FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an Interpretation of FASB Statement No. 109, Accounting for Income Taxes* ("FIN 48"). The adoption did not have a material impact on our consolidated financial statements or effective tax rate and did not result in any unrecognized tax benefits. Interest costs and penalties related to income taxes are classified as interest expense and general and administrative costs, respectively, in our consolidated financial statements. For the year ended December 31, 2008, 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.

#### 10. Employee Benefit Plan.

The Company sponsors a qualified 401(k) Retirement Plan (the "Plan") under which employees are allowed to contribute certain percentages of their pay, up to the maximum allowed under Section 401(k) of the Internal Revenue Code. Company contributions to the Plan are at the discretion of the Board of Directors. The Company did not make any matching contributions for the year ended December 31, 2008.

#### 11. Subsequent Event - Merger with Access Pharmaceuticals, Inc. (Unaudited)

On February 25, 2009 the Company closed its merger with Access Pharmaceuticals, Inc. On July 10, 2008, Access Pharmaceuticals, Inc. (OTC BB: ACCP.OB) announced it had signed an agreement and plan of merger with MacroChem, pursuant to which MacroChem was merged with and into a wholly-owned subsidiary of Access. Holders of MacroChem common shares and in-the money MacroChem warrants receive approximately an aggregate of 2,500,000 shares of common stock of Access as merger consideration at the closing of the merger. All other options and warrants of MacroChem which were unexercised at the Effective Time of the merger were automatically cancelled and void.

In addition to the merger, the noteholders of MacroChem agreed to exchange their notes and interest due on the notes in the total amount of \$859,000 for 859,000 restricted shares of the Access' common stock. The value of the shares issued was determined based on the carrying value of the debt, which was established to be the more readily determinable fair value.

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

#### UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

The following unaudited pro forma condensed combined financial statements apply to the merger between MacroChem and Access, by which MacroChem became a wholly owned subsidiary of Access, and are based upon the historical condensed consolidated financial statements and notes thereto (as applicable) of Access and MacroChem. The unaudited pro forma condensed combined balance sheet gives pro forma effect to the merger as if the merger had been completed on December 31, 2008 and combines Access's December 31, 2008 audited consolidated balance sheet with MacroChem's December 31, 2008 audited consolidated balance sheet. The unaudited pro forma condensed combined statement of operations gives pro forma effect to the merger as if it had been completed on January 1, 2008 and combines Access' audited consolidated statement of operations for the year ended December 31, 2008, with MacroChem's audited consolidated statement of operations for the year ended December 31, 2008.

On February 25, 2009, we closed our acquisition of MacroChem Corporation through the issuance of an aggregate of approximately 2.5 million shares of our common stock. Prior to our acquisition of MacroChem, SCO, an investment company, held a majority of Access' and MacroChem's voting stock. Specifically, SCO owned 53% of the voting stock of Access and 63% of the voting stock of MacroChem. A non-controlling interest of 37% existed at the merger date of MacroChem. In addition, certain members of SCO's management serve on the board of directors of both Access and MacroChem. Based on these facts, Access and MacroChem were deemed under the common control of SCO. As the entities were deemed under common control, the acquisition was recorded using the pooling-of-interest method and beginning in 2009, the financial information for all periods presented will reflect the financial statements of the combined companies in accordance with Appendix D of Statement of Financial Accounting Standards No. 141R (SFAS 141R), "Business Combinations," for entities under common control.

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

In addition, we issued 125,000 shares of Access common stock valued at \$197,000 to former executives of MacroChem for the settlement of employment agreements.

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

The pro forma adjustments are based upon available information and certain assumptions that Access believes are reasonable under the circumstances.

Total consideration paid in connection with the acquisition included:

- Approximately 2.5 million shares of Access common stock was issued to the common shareholders and the in-the-money (\$0.01) warrant holders of MacroChem as consideration having a value of approximately \$3.5 million (the value was calculated using Access' stock price on February 25, 2009 times the shares issued);
- an aggregate of \$106,000 in direct transaction costs; and
- cancelled receivable from MacroChem of \$635,000.

These unaudited pro forma condensed combined financial statements should be read in conjunction with the historical consolidated financial statements and related notes contained in the annual, quarterly and other reports filed by Access and MacroChem with the Securities and Exchange Commission.

#### Pro Forma Condensed Combined Balance Sheet As of December 31, 2008 (Unaudited)

## Historical

	Access MacroChem		Pro Forma Adjustments		Pro Forma Combined		
ASSETS							
Current assets Cash and cash equivalents Receivables	\$	2,663,000 147,000	\$	14,000			\$ 2,677,000 147,000
Receivables due from MacroChem		635,000		-	(635,000)	(f)	-
Prepaid expenses and other current expenses Total current assets		<u>105,000</u> 3,550,000		70,000 84,000			<u>    175,000</u> 2,999,000
Property and equipment, net		87,000		8,000			95,000
Patents net		542,000		457,000			999,000
Other assets		78,000		_			78,000
Total assets	\$	4,257,000	\$	549,000			\$ 4,171,000
LIABILITIES AND STOCKHOLDERS' DEFICIT Current liabilities							
Accounts payable	\$	1,970,000	\$	1,317,000	106,000	(e)	
Accrued expenses		748,000		547,000			1,295,000
Dividends payable		1,896,000		-	(17.000)	(1)	1,896,000
Accrued interest payable		128,000		17,000	(17,000)	(b)	128,000
Current portion of deferred revenue		164,000		5,000	(5,000)	(d)	164,000
Notes payable		-		825,000	(825,000)	(b)	-
Payables due Access		-		635,000	(635,000)	(f)	-
Total current liabilities		4,906,000		3,346,000			6,876,000
Long-term deferred revenue		2,245,000		24,000	(24,000)	(d)	2,245,000
Warrants liability		-		104,000	(104,000)	(d)	-
Long-term debt		5,500,000		-			5,500,000
Total liabilities		12,651,000		3,474,000			14,621,000
Stockholders' equity (deficit) Preferred stock		-		-			-
Common stock		70,000		459,000	25,000 8,000 1,000	(a) (b) (c)	104,000
Additional paid-in capital		127,482,000		97,763,000	(459,000) 508,000 834,000 196,000	(d) (a) (b) (c)	226,783,000
Notes receivable from stockholders		(1,045,000)	)			. /	(1,045,000)
Treasury stock, at cost		(4,000)	)	(59,000)	59,000	(d)	(4,000)
Accumulated deficit		(134,897,000)	) (1	01,088,000 )	(197,000)	(c)	(236,288,000)
					(106,000)	(e)	
Total stockholders' equity (deficit)		(8,394,000)		(2,925,000)			(10,450,000)
Total liabilities and stockholders' equity (deficit)	\$	4,257,000	\$	549,000			\$ 4,171,000

See accompanying Notes to Pro Forma Condensed Combined Balance Sheet

#### Notes to Pro Forma Condensed Combined Balance Sheet

- Note 1: The above statement gives effect to the following pro forma adjustments necessary to reflect the merger of Access and MacroChem, entities deemed under common control, as if the transaction had occurred December 31, 2008.
  - a) To record the exchange, for accounting purposes, by MacroChem shareholders of their common stock and in-the-money warrants for 2,500,000 shares of Access and \$508,000 impact of pro-forma adjustments to additional paid-in capital.
  - b) To record Access common stock exchanged for notes payable of \$825,000 and accrued interest of \$17,000.
  - c) To record Access common stock issued to former executives of MacroChem for the settlement of employment agreements.
  - d) To eliminate the common stock, treasury stock, warrant liabilities and deferred revenue of MacroChem.
  - e) To record \$106,000 in merger costs.
  - f) To eliminate intercompany notes payable/receivable of \$635,000.

After the consummation of the transactions described herein, Access had 100,000,000 common shares authorized, approximately 10,434,474 common shares issued and outstanding, 2,000,000 preferred shares authorized with approximately 3,242.8617 shares of Series A cumulative Convertible Preferred Stock issued and outstanding, convertible into 10,809,539 shares of Access common stock.

#### Pro Forma Condensed Combined Statement of Operations For the Twelve Months Ended December 31, 2008 (Unaudited)

Historical

	 Access	]	MacroChem		Pro Forma Combined
Revenues	\$ 291,000	\$	4,000	\$	295,000
Expenses					
Research and development	12,613,000		10,622,000		23,235,000
General and administrative	4,340,000		3,123,000		7,463,000
Depreciation and amortization	 253,000		71,000		324,000
Total expenses	17,206,000		13,816,000		31,022,000
Loss from operations	(16,915,000)		(13,812,000)		(30,727,000)
Interest and other income	178,000		33,000		211,000
Interest and other expenses	(478,000)		(433,000)		(911,000)
Change in fair value of warrants liability	 -		3,972,000		3,972,000
	(300,000)		3,572,000		3,272,000
Net loss	 (17,215,000)		(10,240,000)		(27,455,000)
Less preferred stock dividends	 (3,358,000)		-		(3,358,000)
Net loss allocable to common stockholders	\$ (20,573,000)	\$	(10,240,000)	\$	(30,813,000)
Basic and diluted loss per common share Loss from operations allocable to all common stockholders	\$ (3.51)	\$	(0.26)	\$	(3.31)
an common subtributers	 <u> </u>	-	<u> </u>	-	
Weighted average basic and diluted common shares outstanding	 5,854,031	_	38,934,207	_	9,321,031

Notes to Pro Forma Condensed Combined Statement of Operations

Note 1: The above statement gives effect to the merger of Access and MacroChem, as if the merger had occurred on January 1, 2008.

Note 2: The pro forma combined-weighted average number of common outstanding shares is based on the weighted average number of shares of common stock of Access during the period plus those shares to be issued in conjunction with the merger. A reconciliation between Access' historical weighted average shares outstanding and pro forma weighted average shares outstanding and pro forma weighted average shares outstanding is as follows:

Historical	5,854,031
MacroChem equivalent shares giving effect to the merger	2,500,000
Shares issued to former MacroChem executives	125,000
Shares issued for notes payable and interest	842,000
Total	9,321,031

\_\_\_\_\_ Units

\$\_\_\_\_\_

## PROSPECTUS

\_\_\_\_\_, 2009

#### 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	\$	1,395
Printing and Engraving Expenses	\$	1,000
Legal Fees and Expenses	\$	15,000
Accountants' Fees and Expenses	\$	10,000
Miscellaneous Costs	<u>\$</u>	10,000
Total	<u>\$</u>	<u>37,395</u>

#### 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 Registrant's Certificate of Incorporation, as amended, and By-laws, as amended, provide for indemnification of officers and directors of the Registrant 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 September 2009, we issued 102,500 shares Access common stock to several consultants 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 2009, we issued 170,000 shares Access common stock to several consultants 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 2009, we issued 70,000 shares Access common stock to several consultants 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 June 9, 2009, we issued 30,000 shares of Access common stock to a former executive of MacroChem for the settlement of his employment agreement. The settlement agreements specify that a portion of the settlement be paid in common stock. 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 2009, we issued 126,667 shares Access common stock to several consultants 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 February 25, 2009, we issued 859,172 shares of Access common stock to cancel approximately \$859,000 of notes and accrued interest due to holders of MacroChem notes. The value of the shares issued was determined based on the carrying value of the debt, which was established to be the more readily determinable fair value. 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 addition, we issued 95,000 shares of Access common stock to former executives of MacroChem for the settlement of employment agreements. The settlement agreements specify that a portion of the settlement be paid in common stock. 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 February 4, 2008, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 272.50 shares of our "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series A Cumulative Convertible Preferred Stock") and agreed to issue warrants to purchase 499,584 shares of our common stock at an exercise price of \$3.50 per share, for an aggregate purchase price for the Series A Cumulative Convertible Preferred Stock and Warrants of \$2,725,000. Proceeds, net of issuance costs from the sale were \$2,444,000. The shares of Series A Cumulative Convertible Preferred Stock at the initial conversion price of \$3.00 per share subject to adjustment.

In addition, \$1,576,000 of Somanta Pharmaceuticals' acquired accounts payable were settled by issuing 538,508 shares of Access common stock and warrants to purchase 246,753 shares of Access common stock at an exercise price of \$3.50 per share. The value of the shares and warrants issued was determined based on the fair value of the accounts payable. 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 7, 2007, we entered into securities purchase agreements (the "Purchase Agreements") with accredited investors whereby we agreed to sell 954.0001 shares of a newly created series of our preferred stock, designated "Series A Cumulative Convertible Preferred Stock", par value \$0.01 per share, for an issue price of \$10,000 per share, (the "Series A Cumulative Convertible 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, subject to adjustment, for an aggregate purchase price for the Series A Cumulative Convertible Preferred Stock and Warrants of \$9,540,001. The shares of Series A Cumulative Convertible Preferred Stock are convertible into common stock at the initial conversion price of \$3.00 per share subject to adjustment.

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

- 2.1 Amended and Restated Agreement of Merger and Plan of Reorganization between Access Pharmaceuticals, Inc. and Chemex Pharmaceuticals, Inc., dated as of October 31, 1995 (Incorporated by reference to Exhibit A of the our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
- 2.2 Agreement and Plan of Merger, by and among Access Pharmaceuticals, Inc., Somanta Acquisition Corporation, Somanta Pharmaceuticals, Inc. Somanta Incorporated and Somanta Limited, dated April 18, 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 Access Pharmaceuticals, Inc., 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-B dated July 12, 1989, Commission File Number 9-9134)
- 3.2 Certificate of Amendment of Certificate of Incorporation filed August 21, 1992
- 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 21, 1995, Commission File No. 33-64031)

II-2

- 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 21, 1995, Commission File No. 33-64031)
- 3.5 Certificate of Amendment of Certificate of Incorporation filed July 18, 1996. (Incorporated by reference to Exhibit 3.8 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)
- Amended and Restated Bylaws (Incorporated by reference to Exhibit 3.1 of our Form 10-Q for the quarter ended June 30, 1996)
   Certificate of Designation of Series A Cumulative Convertible Preferred Stock filed November 9, 2007 (Incorporated by reference
- to Exhibit 3.10 to our Form 10-K for the year ended December 31, 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)
- 5.1\*\* Opinion of Bingham McCutchen LLP
- 10.1\* 1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form S-4 dated December 21, 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 us 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 Company dated November 19, 1996 (Incorporated by reference to Exhibit 10.11 of our Form 10-K for the year ended December 31, 1996)
- 10.5\* Employment Agreement of David P. Nowotnik, PhD (Incorporated by reference to Exhibit 10.19 of our Form 10-K for the year ended December 31, 1999)
- 10.6\* 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10K for the year ended December 31, 1999)
- Form of Convertible Note (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)
   Rights Agreement, dated as of October 31, 2001 between the us and American Stock Transfer & Trust Company, as Rights Agent
- (incorporated by reference to Exhibit 99.1 of our Current Report on Form 8-K dated October 19, 2001)
- 10.9 Amendment to Rights Agreement, dated as of February 16, 2006 between us and American Stock Transfer & Trust Company, as Rights Agent (2)
- 10.10 Amendment to Rights Agreement, dated as of November 9, 2007 between us and American Stock Transfer & Trust Company as Rights Agent
- 10.11\* 2001 Restricted Stock Plan (Incorporated by reference to Appendix A of our Proxy Statement filed on April 16, 2001)
- 10.12\* 2005 Equity Incentive Plan (Incorporated by reference to Exhibit 1 of our Proxy Statement filed on April 18, 2005 (2)
- 10.13\* Employment Agreement, dated as of June 1, 2005 by and between us and Stephen B. Thompson (1)
- 10.14 Asset Sale Agreement, dated as of October 12, 2005, between us and Uluru, Inc. (1)
- 10.15 Amendment to Asset Sale Agreement, dated as of December 8, 2006, between us and Uluru, Inc. (3)
- 10.16 License Agreement, dated as of October 12, 2005, between us and Uluru, Inc. (1)
- 10.17 Form of Warrant, dated February 16, 2006, issued by us to certain Purchasers (2)
- 10.18 Form of Warrant, dated October 24, 2006, issued by us to certain Purchasers (3)
- 10.19 Form of Warrant, December 6, 2006, issued by us to certain Purchasers (3)

II-3

- 10.20\* 2007 Special Stock Option Plan and Agreement, dated January 4, 2007, by and between us and Stephen R. Seiler, President and Chief Executive Officer (4)
- 10.21 Note Purchase Agreement dated April 26, 2007 between us and Somanta Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.42 of our Form 10-Q for the quarter ended June 30, 2007)
- 10.22 Preferred Stock and Warrant Purchase Agreement, dated November 7, 2007, between us and certain Purchasers (5)
- 10.23 Investor Rights Agreement, dated November 10, 2007, between us and certain Purchasers (5)
- 10.24 Form of Warrant Agreement dated November 10, 2007, between us and certain Purchasers (5)
- 10.25 Board Designation Agreement, dated November 15, 2007, between us and SCO Capital Partners LLC (5)
- 10.26 Amendment and Restated Purchase Agreement, dated February 4, 2008 between us and certain Purchasers (5)
- 10.27 Amended and Restated Investor Rights Agreement, dated February 4, 2008 between us and certain Purchasers (5)
- 10.28\* Employment Agreement, dated January 4, 2008 between us and Jeffrey B. Davis (5)
- 23.1 Consent of Whitley Penn LLP
- 23.2 Consent of Whitley Penn LLP
- 23.3 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 15(c) of the report.
  - (1) Incorporated by reference to our Form 10-K for the year ended December 31, 2005.
  - (2) Incorporated by reference to our Form 10-Q for the quarter ended March 31, 2006.
  - (3) Incorporated by reference to our Form 10-K for the year ended December 31, 2006.
  - (4) Incorporated by reference to our Form 10-Q for the quarter ended March 31, 2007.
  - (5) Incorporated by reference to our Form S-1, 333-149633.

\*\* To be filed by amendment

#### 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 of 1933;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent posteffective 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 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

(iii) to include any material information with respect to the plan of distribution not previously disclosed in this Registration Statement or any material change to such information in this Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, 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.

(3) 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 of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions described in Item 24 above, 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 coursel 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 deemed incorporated by reference into 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.

II-5

#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Dallas, State of Texas, on this 26th day of October, 2009.

ACCESS PHARMACEUTICALS, INC.

Date October 26, 2009

By: /s/ Jeffrey B. Davis

Jeffrey B. Davis Chief Executive Officer (Principal Executive Officer)

By: /s/ Stephen B. Thompson Stephen B. Thompson Vice President, Chief Financial Officer and Treasurer (Principal Accounting Officer)

#### POWER OF ATTORNEY

We, the undersigned directors of Access Pharmaceuticals, Inc., hereby severally constitute and appoint Jeffrey B. Davis and Stephen B. Thompson, and both or either one of them, our true and lawful attorneys-in-fact and agents, with full power of substitution and re-substitution in for him and in his name, place and stead, and in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement, and any subsequent registration statements pursuant to Rule 462 of the Securities Act, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that each of said attorneys-in-fact or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Date	October 26, 2009	By:	/s/ Jeffrey B. Davis Jeffrey B. Davis, Director, Chief Executive Officer
Date	October 26, 2009	By:	/s/ Mark J. Ahn Mark J. Ahn, Director
Date	October 26, 2009	By:	/s/ Mark J. Alvino Mark J. Alvino, Director
Date	October 26, 2009	By:	/s/ Esteban Cvitkovic Esteban Cvitkovic, Director
Date	October 26, 2009	By:	/s/ Stephen B. Howell Stephen B. Howell, Director
Date	October 26, 2009	By:	/s/ David P. Luci David P. Luci, Director
Date	October 26, 2009	By:	/s/ Steven H. Rouhandeh Steven H. Rouhandeh, Chairman of the Board

Date October 26, 2009

#### <u>Exhibit</u>

#### <u>Number</u> <u>Description of Document</u>

Exhibit Number

- 2.1 Amended and Restated Agreement of Merger and Plan of Reorganization between Access Pharmaceuticals, Inc. and Chemex Pharmaceuticals, Inc., dated as of October 31, 1995 (Incorporated by reference to Exhibit A of the our Registration Statement on Form S-4 dated December 21, 1995, Commission File No. 33-64031)
- 2.2 Agreement and Plan of Merger, by and among Access Pharmaceuticals, Inc., Somanta Acquisition Corporation, Somanta Pharmaceuticals, Inc. Somanta Incorporated and Somanta Limited, dated April 18, 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 Access Pharmaceuticals, Inc., 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-B dated July 12, 1989, Commission File Number 9-9134)
- 3.2 Certificate of Amendment of Certificate of Incorporation filed August 21, 1992
- 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 21, 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 21, 1995, Commission File No. 33-64031)
- 3.5 Certificate of Amendment of Certificate of Incorporation filed July 18, 1996. (Incorporated by reference to Exhibit 3.8 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 3.1 of our Form 10-Q for the quarter ended June 30, 1996)
- 3.10 Certificate of Designation of Series A Cumulative Convertible Preferred Stock filed November 9, 2007 (Incorporated by reference to Exhibit 3.10 to our Form 10-K for the year ended December 31, 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)
- 5.1\*\* Opinion of Bingham McCutchen LLP
- 10.1\* 1995 Stock Option Plan (Incorporated by reference to Exhibit F of our Registration Statement on Form S-4 dated December 21, 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 us 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 Company dated November 19, 1996 (Incorporated by reference to Exhibit 10.11 of our Form 10-K for the year ended December 31, 1996)
- 10.5\* Employment Agreement of David P. Nowotnik, PhD (Incorporated by reference to Exhibit 10.19 of our Form 10-K for the year ended December 31, 1999)
- 10.6\* 401(k) Plan (Incorporated by reference to Exhibit 10.20 of our Form 10K for the year ended December 31, 1999)
- 10.7 Form of Convertible Note (Incorporated by reference to Exhibit 10.24 of our Form 10-Q for the quarter ended September 30, 2000)

- 10.8 Rights Agreement, dated as of October 31, 2001 between the us and American Stock Transfer & Trust Company, as Rights Agent (incorporated by reference to Exhibit 99.1 of our Current Report on Form 8-K dated October 19, 2001)
- 10.9 Amendment to Rights Agreement, dated as of February 16, 2006 between us and American Stock Transfer & Trust Company, as Rights Agent (2)
- 10.10 Amendment to Rights Agreement, dated as of November 9, 2007 between us and American Stock Transfer & Trust Company as Rights Agent
- 10.11\* 2001 Restricted Stock Plan (Incorporated by reference to Appendix A of our Proxy Statement filed on April 16, 2001)
- 10.12\* 2005 Equity Incentive Plan (Incorporated by reference to Exhibit 1 of our Proxy Statement filed on April 18, 2005 (2)
- 10.13\* Employment Agreement, dated as of June 1, 2005 by and between us and Stephen B. Thompson (1)
- 10.14 Asset Sale Agreement, dated as of October 12, 2005, between us and Uluru, Inc. (1)
- 10.15 Amendment to Asset Sale Agreement, dated as of December 8, 2006, between us and Uluru, Inc. (3)
- 10.16 License Agreement, dated as of October 12, 2005, between us and Uluru, Inc. (1)
- 10.17 Form of Warrant, dated February 16, 2006, issued by us to certain Purchasers (2)
- 10.18 Form of Warrant, dated October 24, 2006, issued by us to certain Purchasers (3)
- 10.19 Form of Warrant, December 6, 2006, issued by us to certain Purchasers (3)
- 10.20\* 2007 Special Stock Option Plan and Agreement, dated January 4, 2007, by and between us and Stephen R. Seiler, President and Chief Executive Officer (4)
- 10.21 Note Purchase Agreement dated April 26, 2007 between us and Somanta Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 10.42 of our Form 10-Q for the quarter ended June 30, 2007)
- 10.22 Preferred Stock and Warrant Purchase Agreement, dated November 7, 2007, between us and certain Purchasers (5)
- 10.23 Investor Rights Agreement, dated November 10, 2007, between us and certain Purchasers (5)
- 10.24 Form of Warrant Agreement dated November 10, 2007, between us and certain Purchasers (5)
- 10.25 Board Designation Agreement, dated November 15, 2007, between us and SCO Capital Partners LLC (5)
- 10.26 Amendment and Restated Purchase Agreement, dated February 4, 2008 between us and certain Purchasers (5)
- 10.27 Amended and Restated Investor Rights Agreement, dated February 4, 2008 between us and certain Purchasers (5)
- 10.28\* Employment Agreement, dated January 4, 2008 between us and Jeffrey B. Davis (5)
- 23.1 Consent of Whitley Penn LLP
- 23.2 Consent of Whitley Penn LLP
- 23.3 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 15(c) of the report.
  - (1) Incorporated by reference to our Form 10-K for the year ended December 31, 2005.
  - (2) Incorporated by reference to our Form 10-Q for the quarter ended March 31, 2006.
  - (3) Incorporated by reference to our Form 10-K for the year ended December 31, 2006.
  - (4) Incorporated by reference to our Form 10-Q for the quarter ended March 31, 2007.
  - (5) Incorporated by reference to our Form S-1, 333-149633.

\*\* To be filed by amendment.

#### CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 31, 2009, accompanying the consolidated financial statements of Access Pharmaceuticals, Inc. as of and for the year ended December 31, 2008, included in the Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2009, which is included in this Registration Statement. We consent to the inclusion in 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 October 27, 2009

### CONSENT OF INDEPENDENT PUBLIC ACCOUNTING FIRM

We have issued our report dated August 25, 2009, accompanying the consolidated financial statements of MacroChem Corporation as of December 31, 2008 and for the year then ended, included in the Current Report on Form 8-K/A of Access Pharmaceuticals, Inc. filed with the Securities and Exchange Commission on August 26, 2009, which is included in this Registration Statement. We consent to the inclusion in 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 October 27, 2009