#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

### FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 2009

OR

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

For the Transition Period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-9314

#### **ACCESS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of (I.R.S. Employer I.D. No.) <u>83-0221517</u>

(I.R.S. Employer I.D. No.)

2600 Stemmons Frwy, Suite 176, Dallas, TX 75207

(Address of principal executive offices)

(214) 905-5100

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  $\square$  No  $\square$ 

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

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):

Large accelerated filer  $\Box$ 

Accelerated filer  $\Box$ 

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

Smaller reporting company  $\square$ 

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

As of November 13, 2009, there were 13,111,382 shares of Access Pharmaceuticals, Inc. common stock outstanding. Also, as of November 13, 2009, there were 2,992.3617 shares of Series A Convertible Preferred Stock outstanding, and such shares were convertible into 9,974,531 shares of common stock.

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#### PART I -FINANCIAL INFORMATION

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

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

#### ITEM 1. FINANCIAL STATEMENTS

The response to this Item is submitted as a separate section of this report.

# ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### **OVERVIEW**

Access Pharmaceuticals, Inc. (together with our subsidiaries, "We", "Access" or the "Company") is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one approved product, one product candidate at Phase 3 of clinical development, three product candidates in Phase 2 of clinical development and other product candidates in pre-clinical development. Further development of our product pipeline is dependent on our ability to enter into collaborative arrangements or to otherwise raise or generate sufficient resources. 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 approval in the U.S. from the Food & Drug Administration ("FDA"). MuGard has been launched in Germany, Italy, UK and Greece by our European commercial partner, SpePharm.
- Our lead product candidate in development 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 generated cumulative 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>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.
- 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
ProLindac <sup>TM</sup> (Polymer	Access / Univ of	Synthetic polymer	Cancer	Phase 2
Platinate, AP5346)	London	porymer		
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" under Item 1 in our Annual Report on Form 10-K for the year endedDecember 31, 2008.

#### **RECENT EVENTS**

On October 6, 2009, we announced the signing of an agreement with iMedicor for the North American launch of MuGard. iMedicor's highly targeted Alerts System application will introduce 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 that 6 to 12 patients will be enrolled this year in advance of enrolling patients in a 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 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.

### 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 September 30, 2009. As of September 30, 2009, our cash and cash equivalents were \$1,672,000 and our net cash burn rate for the nine months ended September 30, 2009, was approximately \$115,000 per month. As of September 30, 2009, our working capital deficit was \$6,252,000. Our working capital deficit at September 30, 2009 represented an increase of \$1,639,000 as compared to our working capital deficit as of December 31, 2008 of \$4,613,000. The increase in the working capital deficit at September 30, 2009 reflects an increase in operating expenses which included manufacturing product scale-up for our new ProLindac trial and MacroChem expenses offset by milestone payments from our licensing agreements. As of September 30, 2009, we had one convertible note outstanding in the principal amount of \$5.5 million which is due September 13, 2011.

As of September 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 and our ability to continue as a going concern.

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 September 30, 2009 of \$245,787,000. 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 are required to seek additional financing sources within the next twelve months. We cannot assure you that we will ever be able to generate significant product revenue or achieve or sustain profitability.

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.

#### THIRD QUARTER 2009 COMPARED TO THIRD QUARTER 2008

Our licensing revenue for the third quarter of 2009 was \$124,000 as compared to \$38,000 for 2008, an increase of \$86,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.



We received royalties of \$20,000 in the third quarter of 2009. There were no royalties in the same period in 2008.

We had sponsored research and development revenue of \$9,000 in 2008. The research and development agreement was completed in 2008.

Total research and development spending for the third quarter of 2009 was \$561,000, as compared to \$1,670,000 for 2008, a decrease of \$1,109,000. The decrease in expenses was primarily due to:

- lower costs for product manufacturing for a new ProLindac clinical trial in 2009 as some manufacturing is complete and a clinical trial has started (\$444,000);
- research and development expenses incurred by MacroChem in the third quarter of 2008, which are no longer ongoing (\$386,000);
- · lower scientific consulting expenses (\$149,000);
- · lower salary and related expenses (\$129,000);
- $\cdot$  other net decreases in research spending (\$92,000); and
- $\cdot\,$  offset by higher expenses due to the cost of option grants (\$91,000).

Total general and administrative expenses were \$3,458,000 for the third quarter of 2009, an increase of \$1,291,000 compared to 2008 expenses of \$2,167,000 for the same quarter. The increase in expenses was due primarily to the following:

- · higher shareholder consultant expenses (\$2,012,000) to inform investors about Access and to expand our shareholder base;
- higher business professional expenses (\$371,000);
- higher expenses due to the cost of option grants (\$89,000);
- offset by general and administrative expenses incurred by MacroChem in the third quarter of 2008 that are no longer ongoing (\$732,000);
- · lower accrual of potential liquidated damages under an investor rights agreement with certain investors (\$205,000);
- · lower director and officer insurance and lower director fees (\$111,000) due to lower insurance costs and directors taking options instead of fees in 2009;
- · lower salary and related expenses (\$83,000); and
- $\cdot$  other net decreases in general and administrative expenses (\$50,000).

Depreciation and amortization was \$65,000 for the third quarter of 2009, as compared to \$80,000 for 2008, a decrease of \$15,000. The decrease in expenses was primarily due to assets becoming fully depreciated.

Total operating expenses for the third quarter of 2009, were \$4,084,000 as compared to total operating expenses of \$3,917,000 for same period in 2008, an increase of \$167,000 for the reasons listed above.

Interest and miscellaneous income was \$2,000 for the third quarter of 2009, as compared to \$32,000 for the same period in 2008, a decrease of \$30,000. The decrease in interest and miscellaneous income was due to lower average cash balances during 2009 versus 2008.

Interest and other expense was \$133,000 for the third quarter of 2009, as compared to \$183,000 in 2008, a decrease of \$50,000. 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 by MacroChem in the second quarter of 2008.

Preferred stock dividends of \$471,000 were accrued for the third quarter of 2009 and \$523,000 for 2008, a decrease of \$52,000. 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 third quarter of 2009, was \$4,542,000, or a \$0.37 basic and diluted loss per common share, compared with a loss of \$4,544,000, or a \$0.55 basic and diluted loss per common share for the same period in 2008, a decreased loss of \$2,000.

### NINE MONTHS ENDED SEPTEMBER 30, 2009 COMPARED TO NINE MONTHS ENDED SEPTEMBER 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 Financial Accounting Standards Board standards on business combinations for entities under common control.

Our licensing revenue for the first nine months of 2009 was \$228,000 as compared to \$77,000 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 received royalties of \$20,000 in the first nine months of 2009. There were no royalties in the same nine month period in 2008.

We had sponsored research and development revenue of \$140,000 in the first nine months of 2008. The research and development agreement was completed in 2008.

Total research and development spending for the first nine months of 2009 was \$1,830,000, as compared to \$22,682,000 for the same period in 2008, a decrease of \$20,852,000. 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);
- 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);
- research and development expenses incurred by MacroChem in the first nine months of 2008, which are no longer ongoing (\$851,000);
- · lower costs for product manufacturing due to the start of a new ProLindac clinical trial (\$1,038,000);
- · lower salary and related expenses (\$189,000);
- · lower scientific consulting expenses (\$210,000);
- · lower travel expenses (\$84,000);
- other net decreases in research spending (\$130,000); and
- offset by higher expenses due to option grants (\$186,000).

Total general and administrative expenses were \$6,212,000 for the first nine months of 2009, a decrease of \$73,000 over 2008 expenses of \$6,285,000. The decrease in spending was due primarily to the following:

- general and administrative expenses incurred by MacroChem in the first nine months of 2008 that are no longer ongoing (\$2,728,000);
- lower director and officer insurance and lower director fees (\$137,000) due to lower insurance costs and directors taking options instead of fees in 2009;
- lower salary and related expenses (\$121,000);
- · lower legal and accounting expenses (\$93,000);
- other net decreases in general and administrative expenses (\$58,000);
- offset by higher shareholder consultant expenses (\$2,165,000) to inform investors about Access and to expand our shareholder base;
- higher business professional expenses (\$737,000); and
- higher expenses due to the cost of option grants (\$162,000).

Depreciation and amortization was \$197,000 for the first nine months of 2009 as compared to \$246,000 for the same period in 2008 reflecting a decrease of \$49,000. The decrease in depreciation and amortization was due to assets becoming fully depreciated.

Total operating expenses for the first nine months of 2009 were \$8,239,000 as compared to total operating expenses of \$29,213,000 for same period in 2008, a decrease of \$20,974,000 for the reasons listed above.

Interest and miscellaneous income was \$18,000 for the first nine months of 2009 as compared to \$173,000 for the same period of 2008, a decrease of \$155,000. The decrease in interest and miscellaneous income was due to lower average cash balances during 2009 versus 2008.

Interest and other expense was \$395,000 for the first nine months of 2009 as compared to \$512,000 in 2008, a decrease of \$117,000. 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 \$1,434,000 were accrued for the first nine months of 2009 and \$2,873,000 for 2008, a decrease of \$1,439,000. The decrease is due to preferred shareholders converting their ownership to common stock in 2009 and beneficial conversion feature in 2008 as discussed below, 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 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 Preferred Stock and was considered to be "in the money" at the time of the agreement to exchange the convertible notes for preferred stock. This resulted in a beneficial conversion feature. The preferred stockholder has the right at any time to convert all or any lesser portion of the Series A Preferred Stock into common stock. This resulted in an intrinsic value of the preferred stock. The difference between the implied value of the preferred stock and the beneficial conversion feature was treated as preferred stock dividends of \$857,000.



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 nine months of 2009 was \$9,802,000, or a \$0.86 basic and diluted loss per common share, compared with a loss of \$32,208,000, or a \$3.97 basic and diluted loss per common share for the same period in 2008, a decreased loss of \$22,406,000.

#### ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

#### ITEM 4T. CONTROLS AND PROCEDURES

Under the supervision and with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Act")) as of September 30, 2009. Based on this evaluation, our CEO and CFO concluded that, as of September 30, 2009, our disclosure controls and procedures were not effective. This conclusion was based on the existence of the material weaknesses in our internal control over financial reporting previously disclosed and discussed below.

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

Our management, including our principal executive officer and principal accounting officer, conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework. Based on its evaluation, our management concluded in our Annual Report on Form 10-K for the year ended December 31, 2008 that there is a material weakness in our internal control over financial reporting. As of the date of this report on Form 10-Q, we have not remediated such material weakness and as a result, our Chief Executive Officer and Chief Financial Officer have concluded that a material weakness continues to exist as of the end of the period covered by this Quarterly Report on Form 10-Q and our disclosure controls and procedures were not effective. The material weakness identified did not result in the restatement of any previously reported financial statements or any related financial disclosure, nor does management believe that it had any effect on the accuracy of the Company's financial statements for the current reporting period. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

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

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

#### Changes In Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2009 that have materially affected, or are reasonable likely to materially affect, our internal control over financial reporting.

#### PART II -- OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

None.

## ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEED

During the third quarter of 2009 we issued 515,500 shares Access common stock to several consultants for their consulting and investor relations fees. 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.

#### ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Pursuant to the terms of the Certificate of Designations, Rights and Preferences of our Series A Cumulative Convertible Preferred Stock, we are required to pay dividends in cash or shares of our common stock, semi-annually, at the rate of 6% per annum. If funds are not currently available to pay cash dividends or if a cash payment of dividends would be impermissible under Delaware law, we may in certain circumstances pay such dividends in shares of the Company's common stock. In order to pay such dividends in shares of the Company's common stock. In order to pay such dividends in shares, the resale must be permissible subject to an exemption from registration, or the respective holders of Series A Preferred Stock must agree to accept restricted common stock as payment of such dividends. In the event none of these three circumstances are met, and the dividends have not been paid in cash or shares of the Company's common stock, the dividends shall continue to accrue until they are paid in cash or shares of the Company's common stock. The Company has accrued as of September 30, 2009, dividends payable of \$2,294,000.

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 with respect to certain shares issuable upon conversion of our outstanding preferred stock. As of September 30, 2009, the Securities and Exchange Commission had not yet declared a registration statement effective with respect to all of the shares covered by the Investor Rights Agreement, and as a result, the Company accrued \$1,153,000 in liquidated damages as of September 30, 2009. A registration statement filed by Access relating to a portion of such securities was declared effective on November 13, 2008.

In addition, the Company has a convertible note in the principal amount of \$5,500,000 outstanding. Interest on the note is due annually and was due on September 13, 2009 in the amount of \$423,500. The Company has received an extension for the interest due from the noteholder in this regard and is currently negotiating a mutually acceptable payment plan.

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

None

ITEM 5. OTHER INFORMATION

None

ITEM 6. EXHIBITS

Exhibits:

- 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.
- 3.0 Articles of incorporation and bylaws:
- 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 Designations, Rights and Preferences of Series A Cumulative Convertible Preferred Stock (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)
- 31.1 Certification of Chief Executive Officer of Access Pharmaceuticals, Inc. pursuant to Rule 13a-14(a)/15d-14(a)
- 31.2 Certification of Chief Financial Officer of Access Pharmaceuticals, Inc. pursuant to Rule 13a-14(a)/15d-14(a)
- 32.1\* Certification of Chief Executive Officer of Access Pharmaceuticals, Inc. pursuant to 18 U.S.C. Section 1350
- 32.2\* Certification of Chief Financial Officer of Access Pharmaceuticals, Inc. pursuant to 18 U.S.C. Section 1350

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

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

# ACCESS PHARMACEUTICALS, INC.

Date:November 16, 2009	By:	/s/ Jeffrey B. Davis
		Jeffrey B. Davis
		Chief Executive Officer
		(Principal Executive Officer)
Date:November 16, 2009	By:	/s/ Stephen B. Thompson
		Stephen B. Thompson
		Vice President and Chief Financial Officer
		(Principal Financial and Accounting Officer

Condensed Consolidated Balance Sheets

ASSETS	September 30, 2009	December 31, 2008			
	(unaudited)	(unaudited)			
		(See Note 4)			
Current assets					
Cash and cash equivalents	\$ 1,672,000	\$ 2,677,000			
Receivables	23,000	147,000			
Prepaid expenses and other current assets	45,000	175,000			
Total current assets	1,740,000	2,999,000			
		i			
Property and equipment, net	59,000	95,000			
Patents, net	840,000	999,000			
Other assets	66,000	78,000			
Total assets	\$ 2,705,000	\$ 4,171,000			
LIABILITIES AND STOCKHOLDERS' DEFICIT					
Current liabilities					
Accounts payable	\$ 3,692,000	\$ 3,287,000			
Accrued expenses	1,208,000	1,295,000			
Dividends payable	2,294,000	1,896,000			
Accrued interest payable	446,000	145,000			
Notes payable	-	825,000			
Current portion of deferred revenue	352,000	164,000			
Total current liabilities	7,992,000	7,612,000			
Long-term deferred revenue	4,812,000	2,245,000			
Long-term debt	5,500,000	5,500,000			
Total liabilities	18,304,000	15,357,000			
Commitments and contingencies					
Stockholders' deficit					
Convertible Series A preferred stock - \$.01 par value; authorized					
2,000,000 shares; 2,992.3617 issued and outstanding at					
September 30, 2009 and 3,242.8617 at December 31, 2008	-	-			
Common stock - \$.01 par value; authorized 100,000,000 shares;					
issued, 13,111,545 at September 30, 2009 and 9,467,474 at					
December 31, 2008	131,000	95,000			
Additional paid-in capital	231,106,000	225,753,000			
Notes receivable from stockholders	(1,045,000)	(1,045,000)			
Treasury stock, at cost – 163 shares	(4,000)	(4,000)			
Accumulated deficit	(245,787,000)	(235,985,000)			
Total stockholders' deficit	(15,599,000)	(11,186,000)			
Total liabilities and stockholders' deficit	\$ 2,705,000	\$ 4,171,000			

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

# Condensed Consolidated Statements of Operations (unaudited)

	Three months September 30		Nine months ended September 30,			
	2009 2008		2009	2008		
		(See Note 4)	(See Note 4)	(See Note 4)		
Revenues						
License revenues	\$ 124,000	\$ 38,000	\$ 228,000	\$ 77,000		
Royalties	20,000	-	20,000	-		
Sponsored research and development	-	9,000		140,000		
Total revenues	144,000	47,000	248,000	217,000		
Expenses						
Research and development	561,000	1,670,000	1,830,000	22,682,000		
General and administrative	3,458,000	2,167,000	6,212,000	6,285,000		
Depreciation and amortization	65,000	80,000	197,000	246,000		
Total expenses	4,084,000	3,917,000	8,239,000	29,213,000		
Loss from operations	(3,940,000)	(3,870,000)	(7,991,000)	(28,996,000)		
Interest and miscellaneous income	2,000	32,000	18,000	173,000		
Interest and other expense	(133,000)	(183,000)	(395,000)	(512,000)		
	(131,000)	(151,000)	(377,000)	(339,000)		
Net loss	(4,071,000)	(4,021,000)	(8,368,000)	(29,335,000)		
Less preferred stock dividends	471,000	523,000	1,434,000	2,873,000		
Net loss allocable to common stockholders	\$ (4,542,000)	\$ (4,544,000)	\$ (9,802,000)	\$ (32,208,000)		
Basic and diluted loss per common share						
Net loss allocable to common shareholders	\$ (0.37)	\$ (0.55)	\$ (0.86)	\$ (3.97)		
Weighted average basic and diluted common shares outstanding	12,204,696	8,303,457	11,375,793	8,107,247		

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

#### Condensed Consolidated Statement of Stockholders' Deficit (unaudited)

			(una	uallea)		Notes		
	Common Stock			ed Stock	Additional paid-in capital	receivable from	Treasury stock	Accumulated deficit
	Shares	Amount	Shares	Amount		stockholders		
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)	¢(225.085.000)
Common stock issued for	9,467,000	\$ 95,000	3,242.8017	\$ -	\$225,755,000	\$(1,043,000)	\$ (4,000)	\$(235,985,000)
preferred dividends Warrants issued for	894,000	9,000	-	-	847,000	-	-	-
services	-	-	-	-	24,000	-	-	-
Stock option compensation expense Common stock issued to MacroChem noteholders	-	-	-	-	56,000	-	-	-
for notes and accrued interest	859,000	8,000	-	-	851,000	-	-	-
Common stock issued to former MacroChem	05.000	1 000			122 000			
executives Preferred dividends	95,000	1,000	-	-	132,000	-	-	- (480,000)
Net loss		-						(2,089,000)
Balance at March 31, 2009	11,315,000	113,000	3,242.8617	-	227,663,000	(1,045,000)	(4,000)	(238,554,000)
Warrants issued for services	-	-	-	-	27,000	-	-	-
Stock option compensation expense	-	-	-	-	252,000	-	-	_
Preferred stock converted	117.000	1 000	(25,0000)					
into common stock Common stock issued to former MacroChem	117,000	1,000	(35.0000)	-	(1,000)	-	-	-
executives Common stock issued for cash exercise of	30,000	-	-	-	64,000	-	-	-
options Restricted common stock	25,000	-	-	-	14,000	-	-	-
issued for services	127,000	2,000	-	-	314,000	-	-	-
Preferred dividends Net loss	-	-	-	-	-	-	-	(483,000) (2,208,000)
Balance at June 30, 2009	11,614,000	116,000	3,207.8617		228,333,000	(1,045,000)	(4,000)	(241,245,000)
Warrants issued for					502.000			
services Stock option	-	-	-	-	503,000	-	-	-
compensation expense Preferred stock converted	-	-	-	-	285,000	-	-	-
into common stock Common stock issued for	719,000	8,000	(215.5000)	-	(8,000)	-	-	-
preferred dividends Common stock issued	21,000	-	-	-	71,000	-	-	-
for cash exercise of options	210,000	2,000	-	-	142,000	-	-	-
Common stock issued for warrant exercises	33,000	-	-	-	-	-	-	-
Restricted common stock issued for services	515,000	5,000	-	-	1,780,000	-	-	-
Preferred dividends Net loss	-	-	-	-	-	-	-	(471,000) (4,071,000)
Balance at September 30, 2009	13,112,000	\$ 131,000	2,992.3617	\$	\$231,106,000	\$(1,045,000)	\$ (4,000)	\$(245,787,000)

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

# Condensed Consolidated Statements of Cash Flows (unaudited)

	N	Nine Months ended September		
		2009	.u 50	2008
Cash flows from operating activities:		2007		2008
Net loss	\$	(8,368,000)	\$	(29,335,000)
Adjustments to reconcile net loss to net cash used in operating activities:	-	(*,***,***)	-	(,,,,)
Depreciation and amortization		197,000		245,000
Stock option compensation expense		593,000		899,000
Stock and warrants issued for services		2,852,000		427,000
Acquired in-process research and development		-		18,536,000
Change in operating assets and liabilities:				
Receivables		124,000		(295,000)
Prepaid expenses and other current assets		130,000		(121,000)
Other assets		12,000		-
Accounts payable and accrued expenses		318,000		317,000
Dividends payable		(109,000)		(25,000)
Accrued interest payable		334,000		315,000
Deferred revenue		2,755,000		1,475,000
Net cash used in operating activities		(1,162,000)		(7,562,000)
		() ()		(1) 1 1 1 1
Cash flows from investing activities:				(21.000)
Capital expenditures		(2,000)		(31,000)
Proceeds from sale of asset		1,000		-
Redemptions of short-term investments and certificate of deposits		_		3,104,000
Virium acquisition by MacroChem, net of cash acquired		_		(240,000)
Somanta acquisition, net of cash acquired		_		(65,000)
Net cash provided by (used in) investing activities		(1,000)		2,768,000
Net cash provided by (used in) investing activities		(1,000)		2,708,000
Cash flows from financing activities:				
Proceeds from debt issuance		-		625,000
Payments of notes payable		-		(639,000)
Proceeds from exercise of common stock options		158,000		15,000
Proceeds from preferred stock issuances, net of costs		_		2,444,000
Net cash provided by financing activities		158,000		2,445,000
Net decrease in cash and cash equivalents		(1,005,000)		(2,349,000)
Cash and cash equivalents at beginning of period		2,677,000		2,582,000
Cash and cash equivalents at end of period	\$	1,672,000	\$	233,000
Supplemental cash flow information: Cash paid for interest	\$	-	\$	9,000
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Supplemental disclosure of noncash transactions:				
Shares issued for payables, notes payable and accrued interest		859,000		1,576,000
Shares issued for dividends on preferred stock		927,000		-
Preferred stock dividends in dividends payable		1,434,000		2,873,000
Beneficial conversion feature –				057 000
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.

Notes to Condensed Consolidated Financial Statements Three and Nine Months Ended September 30, 2009 and 2008 (unaudited)

#### (1) Interim Financial Statements

The consolidated balance sheet as of September 30, 2009, and the consolidated statements of operations and cash flows for the three and nine months ended September 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 September 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 Financial Accounting Standards Board standards on business combinations for entities under common control. See also Note 4.



#### (2) Intangible Assets

Intangible assets consist of the following (in thousands):

	 September 30, 2009			December 31, 2008		
	Gross carrying Accumulated value amortization			Gross carrying value	Accumulated Amortization	
Amortizable intangible assets	 		winerviewich	, and e	TIMOTULWION	
Patents	\$ 2,624	\$	1,784	\$ 2,624	\$1,625	

Amortization expense related to intangible assets totaled \$53,000 and \$159,000 for each of the three and nine months ended September 30, 2009 and totaled \$53,000 and \$159,000 for each of the three and nine months ended September 30, 2008. The aggregate estimated amortization expense for intangible assets remaining as of September 30, 2009 is as follows (in thousands):

2009 2010 2011 2012 2013	\$ 53 212 212 82 44
over 5 years	237
Total	\$ 840

## (3) Liquidity

The Company incurred significant losses allocable to common stockholders of \$9,802,000 for the nine months ended September 30, 2009 and \$32,208,000 for the year ended December 31, 2008. At September 30, 2009, our working capital deficit was \$6,252,000. 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 will be required to seek additional financing sources and enter into future licensing agreements for our products. 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.

#### (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 Financial Accounting Standards Board standards on business combinations for entities under common control.

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

In addition, we issued 125,000 shares of 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 September 30, 2009 and the combined MacroChem financial data for the nine months ended September 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	\$ 3,550,000	\$ 84,000	\$ 2,999,000
Total assets	4,257,000	549,000	4,171,000
Current liabilities	4,906,000	3,346,000	7,612,000
Long-term deferred revenue	2,245,000	24,000	2,245,000
Long-term debt	5,500,000	-	5,500,000
Stockholders' deficit	(8,394,000)	(2,925,000)	(11,186,000)

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

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

	For the nine months ended September 30, 2009			For the year ended December 31, 2008			
	Access Pharmaceuticals	MacroChem Corporation	Combined	Access Pharmaceuticals	MacroChem Corporation	Combined	
Total revenues	\$ 248,000	\$ -	\$ 248,000	\$ 291,000	\$ 4,000	\$ 295,000	
Expenses Research and development General and administrative	1,830,000 6,020,000		1,830,000 6,212,000	12,613,000 4,340,000	10,622,000 3,123,000	23,235,000 7,463,000	
Depreciation and amortization	156,000	41,000	197,000	253,000	71,000	324,000	
Total expenses	8,006,000	233,000	8,239,000	17,206,000	13,816,000	31,022,000	
Loss from operations	(7,758,000	) (233,000)	(7,991,000)	(16,915,000)	(13,812,000)	(30,727,000)	
Interest and miscellaneous income Interest and other expense Gain on change in value of warrant liability	18,000 (369,000		18,000 (395,000)	178,000 (478,000)	33,000 (433,000) 3,972,000	211,000 (911,000) 3,972,000	
	(351,000		(377,000)	(300,000)	3,572,000	3,272,000	
Loss from operations Less preferred stock	(8,109,000	) (259,000)	(8,368,000)	(17,215,000)	(10,240,000)	(27,455,000)	
dividends	(1,434,000	)	(1,434,000)	(3,358,000)		(3,358,000)	
Net loss allocable to common stockholders	\$ (9,543,000	) <u>\$ (259,000)</u>	\$ (9,802,000)	<u>\$ (20,573,000)</u>	\$ (10,240,000)	<u>\$ (30,813,000</u> )	
Basic and diluted loss per common share Net loss allocable to common stockholders Weighted average basic and diluted common	-	-	\$ (0.86)	-	-	\$ (3.69)	
shares outstanding	-	-	11,375,793	-	-	8,354,031	
	For the nine mo Access	onths ended Septer MacroChem	mber 30, 2008	For the three me Access	onths ended Septe MacroChem	mber 30, 2008	
	Pharmaceuticals	Corporation	Combined	Pharmaceuticals	Corporation	Combined	
Total revenues	\$ 217,000	\$ 3,000	\$ 220,000	\$ 47,000	\$ 1,000	\$ 48,000	
Expenses Research and development General and administrative Depreciation and amortization Total expenses	12,108,000 3,372,000 <u>197,000</u> 15,677,000	10,574,000 2,913,000 <u>49,000</u> 13,536,000	22,682,000 6,285,000 246,000 29,213,000	1,284,000 1,439,000 <u>66,000</u> 2,789,000	386,000 728,000 <u>14,000</u> 1,128,000	1,670,000 2,167,000 <u>80,000</u> 3,917,000	
i otai expenses	13,077,000	13,330,000	29,213,000	2,709,000	1,120,000		
Loss from operations	(15,460,000)	(13,533,000)	(28,993,000)	(2,742,000)	(1,127,000)	(3,869,000)	
Interest and miscellaneous income Interest and other expense Gain (loss) on change in warrant value	167,000 (351,000)	6,000 (161,000) 3,886,000	173,000 (512,000) 3,886,000	62,000 (126,000)	(86,000) 419,000	62,000 (212,000) 419,000	
warrant value	(184,000)	3,731,000	3,547,000	(64,000)	333,000	269,000	
Loss from operations Less preferred stock	(15,644,000)	(9,802,000)	(25,446,000)	(2,806,000)	(794,000)	(3,600,000)	
dividends	(2,873,000)		(2,873,000)	(523,000)		(523,000)	
Net loss allocable to common stockholders	<u>\$ (18,517,000)</u>	\$ (9,802,000)	\$ (28,319,000)	\$ (3,329,000)	<u>\$ (794,000)</u>	\$ (4,123,000)	
Basic and diluted loss per common share Net loss allocable to common stockholders Weighted average basic and diluted common shares outstanding	-	-	\$ (3.49) 8,107,242	-	-	\$ (0.50) 8,303,457	
č			22				

#### (5) Stock Based Compensation

For the three and nine months ended September 30, 2009 we recognized stock-based compensation expense of \$285,000 and \$593,000. For the three and nine months ended September 30, 2008 we recognized stock-based compensation expense of \$226,000 and \$899,000.

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

	Three months ended September 30,			Nine months ended September 30,				
	2009		2008		2009		2008	
Research and development General and administrative	\$	130,000 155,000	\$	39,000 187,000	\$	250,000 343,000	\$	78,000 821,000
Stock-based compensation expense included in operating expense	\$	285,000	\$	226,000	\$	593,000	\$	899,000

We granted no stock options during the third 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 nine months grants are as follows:

	9/30/09			
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) Fair Value of Financial Instruments

FASB accounting standards require 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.

## (7) Subsequent Events

In preparing these financial statements, the Company has evaluated events and transactions for potential recognition or disclosure through November 13, 2009, the date the financial statements were issued.

# CERTIFICATION

I, Jeffrey B. Davis, certify that:

- 1. I have reviewed this report on Form 10-Q of Access Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2009

<u>/s/ Jeffrey B. Davis</u> Jeffrey B. Davis Chief Executive Officer

# CERTIFICATION

I, Stephen B. Thompson, certify that:

- 1. I have reviewed this report on Form 10-Q of Access Pharmaceuticals, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this quarterly report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 16, 2009

<u>/s/ Stephen B. Thompson</u> Stephen B. Thompson Chief Finance Officer

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

The certification set forth below is hereby made solely for the purpose of satisfying the requirements of Section 906 of the Sarbanes-Oxley Act of 2002 and may not be relied upon or used for any other purposes.

In connection with the Quarterly Report of Access Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jeffrey B. Davis, Chief Executive Officer certify pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Signed at the City of Dallas, in the State of Texas, this 16th day of November, 2009.

<u>/s/ Jeffrey B. Davis</u> Jeffrey B. Davis Chief Executive Officer

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

The certification set forth below is hereby made solely for the purpose of satisfying the requirements of Section 906 of the Sarbanes-Oxley Act of 2002 and may not be relied upon or used for any other purposes.

In connection with the Quarterly Report of Access Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephen B. Thompson, Chief Finance Officer certify pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement required by Section 906 or other document authenticating, acknowledging or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Signed at the City of Dallas, in the State of Texas, this 16th day of November, 2009.

<u>/s/ Stephen B. Thompson</u> Stephen B. Thompson Chief Finance Officer