

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, 2012  
or

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

For the transition period from \_ to

Commission file number 0-9314

**ACCESS PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation or organization)

83-0221517

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

**2600 Stemmons Freeway, 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  No

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

Indicate by check mark 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  Accelerated filer  Non-accelerated filer  Smaller reporting company

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

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- Common shares, \$0.01 par value - 24,196,734 shares issued and outstanding as of November 14, 2012
  - Series A Convertible Preferred Stock, \$0.01 par value - 2,938.3617 shares issued and outstanding as of November 14, 2012 and convertible into 58,767,234 shares of common stock
  - Series B Cumulative Convertible Preferred Stock, \$0.01 par value – 1,000 shares issued and outstanding as of November 14, 2012 and convertible into 20,000,000 shares of common stock
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ACCESS PHARMACEUTICALS, INC.

INDEX

	Page No.	
PART I - FINANCIAL INFORMATION		
Item 1.	Financial Statements:	
	Condensed Consolidated Balance Sheets at September 30, 2012 (unaudited) and December 31, 2011	16
	Condensed Consolidated Statements of Operations (unaudited) for the three and nine months ended September 30, 2012 and September 30, 2011	17
	Condensed Consolidated Statement of Stockholders' Deficit (unaudited) for the three and nine months ended September 30, 2012	18
	Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2012 and September 30, 2011	19
	Notes to Unaudited Condensed Consolidated Financial Statements	20
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	2
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	11
Item 4.	Controls and Procedures	11
PART II - OTHER INFORMATION		
Item 1.	Legal Proceedings	12
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	13
Item 3.	Defaults Under Senior Securities	13
Item 4.	Mine Safety Disclosures	13
Item 5.	Other Information	13
Item 6.	Exhibits	14
SIGNATURES		15

## PART I – FINANCIAL INFORMATION

*This Quarterly Report on Form 10-Q (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 on Form 10-Q, documents incorporated by reference and other documents and reports that we file periodically with the Securities and Exchange Commission (“SEC”). 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, the adequacy of our capital resources, and revenues from sales and license agreements, and our ability to secure additional financing for our operations. These statements relate to future events or our future financial performance and are based on current expectations, estimates, forecasts and projections and management’s beliefs and assumptions. 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 are difficult to predict and which 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 on Form 10-Q 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 and medical device products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one marketed product, one product at Phase 2 of clinical development and several products in pre-clinical development. The success of our low priority clinical and pre-clinical programs will be dependent on our ability to enter into collaboration arrangements. Certain of our development programs are currently on hold and are dependent upon our ability to secure approved funding for such projects.

## Marketed Product

- MuGard™ is our marketed product for the management of oral mucositis, a frequent side-effect of cancer therapy for which there is no established treatment. The market for mucositis treatment is estimated to be in excess of \$1 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the FDA. We launched MuGard in the United States in the fourth quarter of 2010. We are continuing the training of our third-party MuGard representatives on the product, the oral mucositis condition and our sales strategy. MuGard prescriptions are growing quarterly and we have placed emphasis on our sampling and marketing efforts to build demand, grow oncologist awareness and increase payer uptake. MuGard has been launched in Germany, Italy, the UK, Greece and the Nordic countries by SpePharm, formerly our commercial partner in the E.U. By mutual agreement, the partner agreement with SpePharm has been terminated. Per terms of the agreement, MuGard will continue to be commercially available for up to six months in Europe through SpePharm. We are actively seeking a new European commercial partner for MuGard. Our China partners have received an acceptance letter from the State Food and Drug Administration of the People's Republic of China which provides marketing approval in China. MuGard has been manufactured in the U.S. and shipped to China for sale. Our China partners anticipate commencing sales of MuGard in China in the first quarter of 2013.

## Product Candidates

- Our lead development candidate for the treatment of cancer is ProLindac™, a nanopolymer DACH-platinum prodrug. We initiated a study of ProLindac combined with Paclitaxel in second line treatment of platinum pretreated advanced ovarian cancer patients in the fourth quarter of 2010. This multi-center study of up to 25 evaluable patients is being conducted in France. A second combination study was initiated in the fourth quarter of 2011 combining ProLindac with gemcitabine for the treatment of cholangiocarcinoma. We are currently evaluating data from the trials to decide on how to proceed. Clinical studies of other indications including liver, colorectal and ovarian cancer are under consideration by Jiangsu Aosaikang Pharmaceutical Co., Ltd, our licensee for ProLindac in China. The DACH-platinum incorporated in ProLindac is the same active moiety as that in oxaliplatin (Eloxatin; Sanofi-Aventis), which has had annual sales in excess of \$2.0 billion.
- CobOral® is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We were developing a product for the oral delivery of insulin, and had conducted sponsored development of a product for oral delivery of a number of peptides and RNAi therapeutics. We are currently searching for partners to license this technology.
- CodaCyte®-mediated targeted delivery is a preclinical technology which makes use of the fact that cell surface receptors for vitamins such as B12 are often overexpressed by certain cells, including many cancers. This technology uses nanopolymer constructs to deliver more anti-cancer drug to tumors while protecting normal tissues. We are currently searching for partners to license this technology.

Thiarabine, or 4-thio Ara-C, a next generation nucleoside analog which was licensed from Southern Research Institute. Previously named SR9025 and OSI-7836, the compound has been in two Phase 1/2 solid tumor human clinical trials and was shown to have anti-tumor activity. We were working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and had initiated additional Phase 2 clinical trials in adult AML, ALL and other indications. In the third quarter we terminated our license with Southern Research Institute, terminated the trial and are no longer proceeding with this product.

## Products and Product Candidates

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

### Access Drug Portfolio

Compound	Originator	Technology	Indication	Clinical Stage (1)
MuGard™	Access	Mucoadhesive liquid	Mucositis	Launched U.S. and EU Regulatory Approval China
ProLindac™ (Polymer Platinate, AP5346) (2)	Access / Univ of London	Synthetic polymer	Cancer	Phase 2
Oral Insulin	Access	Cobalamin	Diabetes	Pre-clinical
CobOral® Delivery System	Access	Cobalamin	Various	Pre-clinical
CobaCyte®-Targeted Therapeutics	Access	Cobalamin	Anti-tumor	Pre-clinical

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

## RECENT EVENTS

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

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

Two patient populations were analyzed in the trial; all patients who had completed MuGard treatments (the EFF population) and all patients randomized to participate (FAS). Patients taking MuGard throughout their treatment regimen had a statistically significant reduction in pain. MuGard patients in the EFF and FAS populations both experienced a statistically significant delay to onset of oral mucositis ( $p=0.020$  and  $p=0.007$ , respectively). MuGard patients in the EFF and FAS populations both experienced a statistically significant delay in time to first occurrence  $p=0.022$  and  $p=0.009$ , respectively). MuGard patients in the EFF population experienced a statistically significant reduction in weight loss ( $p=0.036$ ) between their start and completion of radiation treatment.

On March 5, 2012, we announced that our MuGard partner in China, Rhei Pharmaceuticals HK Ltd. (“Rhei”), received regulatory and marketing approval for MuGard from the State Food and Drug Administration to treat oral mucositis in cancer patients.

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

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

## **LIQUIDITY AND CAPITAL RESOURCES**

We have funded our operations primarily through private sales of common stock, preferred stock, convertible notes and through licensing agreements. Our principal source of liquidity is cash and cash equivalents. Product sales and royalty revenues provided limited funding for operations during the nine months ended September 30, 2012. As of September 30, 2012, our cash and cash equivalents were \$106,000 and our net cash burn rate for the nine months ended September 30, 2012, was approximately \$231,000 per month. As of September 30, 2012, our working capital deficit was \$8,135,000. Our working capital deficit at September 30, 2012 represented a decrease of \$742,000 as compared to our working capital deficit as of December 31, 2011 of \$8,877,000. The increase in the working capital deficit at September 30, 2012 reflects nine months of net operating costs. As of September 30, 2012, we had one secured promissory note outstanding in the principal amount of \$2.75 million that was due on September 13, 2012. On November 2, 2012 we repaid in full to such promissory note in the principal amount of \$2.75 million, plus accrued interest. The note and the security agreement are terminated and no further amounts are owed under the note or the security agreement.

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

As of November 14, 2012, we did not have enough capital to achieve our long-term goals. If we raise additional funds by selling equity securities, the relative equity ownership of our existing investors will be diluted and the new investors could obtain terms more favorable than previous investors. A failure to obtain necessary additional capital in the future could jeopardize our operations and our ability to continue as a going concern.

We reduced staff through layoffs, reduced hours for other staff and the executive officers have deferred a portion of their salary in order to conserve cash for operations.

We have incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of September 30, 2012 of \$287,123,000. We expect that our capital resources, revenues from MuGard sales and expected receipts due under our license agreements will be adequate to fund our current level of operations into the 4th quarter of 2013. 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. We cannot assure you that we will ever be able to generate significant product revenue or achieve or sustain profitability.

Since our inception, we have devoted our resources primarily to fund our research and development programs. We have been unprofitable since inception and to date have received limited revenues from the sale of products. We cannot assure you that we will be able to generate sufficient product revenues to attain profitability on a sustained basis or at all. We expect to incur losses for the next several years as we continue to invest in product research and development, preclinical studies, clinical trials and regulatory compliance.

### **THIRD QUARTER 2012 COMPARED TO THIRD QUARTER 2011**

Product sales of MuGard in the United States totaled \$781,000 for the third quarter of 2012 as compared with \$82,000 for the same period of 2011, an increase of \$699,000, due to increased sales and acceptance of our product. See sales table in Critical Accounting Policies and Estimates Relating to MuGard.



Our licensing revenue for the third quarter of 2012 was \$62,000 as compared to \$936,000 for the same period of 2011, a decrease of \$874,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. In 2011 we recorded a one-time recognition of license revenue from the termination of our license with Korean partner.

We recorded royalty revenue for MuGard in Europe of \$28,000 for third quarter of 2012 as compared to \$23,000 for the same period of 2011, an increase of \$5,000.

Total research and development spending for the third quarter of 2012 was \$308,000, as compared to \$906,000 for the same period of 2011, a decrease of \$598,000. The decrease in expenses was primarily due to:

- decreased clinical development with trials for ProLindac, MuGard and Thiarabine (\$296,000);
- decreased salary and related costs (\$127,000) from reduced scientific staff;
- decreased stock compensation expense for lower expense of option grants for research and development employees (\$98,000);
- decreased scientific consulting costs (\$67,000); and
- other net decreases in research spending (\$10,000).

Product costs for MuGard in the United States were \$79,000 for the third quarter of 2012 as compared to \$61,000 for the same period in 2011, an increase of \$18,000.

Total selling, general and administrative expenses were \$1,422,000 for the third quarter of 2012, a decrease of \$380,000 compared to the same period in 2011 of \$1,802,000. The decrease in expenses was due primarily to the following:

- decreased general business consulting expenses due to less use of outside consultants in 2012 (\$394,000) versus the same period in 2011;
- decreased stock compensation expense for lower expense of option grants for selling, general and administrative employees (\$161,000);
- decreased salary and related costs (\$140,000) from reduced general and administrative staff;
- decreased net other general and administrative expenses (\$46,000); and
- increased MuGard product selling expenses (\$361,000).

Depreciation and amortization was \$18,000 for the third quarter of 2012 as compared to \$56,000 for the same period in 2011, a decrease of \$38,000, due to assets being fully depreciated.

Total operating expenses for the third quarter of 2012 were \$1,827,000 as compared to total operating expenses of \$2,825,000 for the same period of 2011, a decrease of \$998,000 for the reasons listed above.

Interest and miscellaneous income was \$111,000 for the third quarter of 2012 as compared to \$1,283,000 for the same period of 2011, a decrease of \$1,172,000. Miscellaneous income was higher in 2011 due to negotiated payables and write-offs of other accounts payable that occurred in 2011.

Interest and other expense was \$186,000 for the third quarter of 2012 as compared to \$237,000 in the same period of 2011, a decrease of \$51,000. The decrease in interest and other expense was due to a pay down in the secured promissory note of \$2.75 million.

We recorded a gain related to warrants classified as derivative liabilities of \$64,000 for the third quarter of 2012 as compared to \$1,138,000 for the same period of 2011. We recorded a derivative for warrants in 2009 when the fair value of the warrants that were issued with our Series A Convertible Preferred Stock were reclassified from equity per the requirements of accounting guidance as a result of the repricing feature.

We recorded a loss for the derivative liability related to preferred stock of \$13,900,000 for the third quarter of 2012 and a loss of \$50,000 for the same period of 2011. We recorded a derivative in 2010 per the requirements of accounting guidance due to the possibility of repricing our Series A Convertible Preferred Stock if we sold our common stock at a price below the original conversion price.

Preferred stock dividends of \$444,000 were accrued for the third quarter of 2012 and \$447,000 for the same period of 2011, a decrease of \$3,000. Dividends are due semi-annually in either cash or common stock.

Net loss allocable to common stockholders for the third quarter of 2012 was \$15,311,000, or a \$0.63 basic and diluted loss per common share, compared with a net loss of \$97,000, or a \$0.00 basic and diluted loss per common share, for the same period in 2011, an increased loss of \$15,214,000.

#### **NINE MONTHS ENDED SEPTEMBER 30, 2012 COMPARED TO NINE MONTHS ENDED SEPTEMBER 30, 2011**

Product sales of MuGard in the United States totaled \$1,950,000 for the first nine months of 2012 as compared to \$137,000 for the same period of 2011, an increase of \$1,813,000 due to increased sales and acceptance of our product. See sales table in Critical Accounting Policies and Estimates Relating to MuGard.

Our licensing revenue for the first nine months of 2012 was \$1,384,000 as compared to \$1,110,000 for 2011, an increase of \$274,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. In the first quarter of 2012, we finalized the negotiations for the termination of the license with SpePharm for MuGard and recognized all of the previously received license fees (\$706,000) that were recorded in deferred revenue and a \$500,000 termination fee.

We recorded royalty revenue for MuGard in Europe of \$64,000 for the first nine months of 2012 as compared to \$64,000 for 2011.

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

Total research and development spending for the first nine months of 2012 was \$1,712,000, as compared to \$2,822,000 for 2011, a decrease of \$1,110,000. The decrease in expenses was primarily due to:

- decreased clinical development with trials for ProLindac, MuGard and Thiarabine (\$625,000);
- decreased stock compensation expense for lower expense of option grants for research and development employees (\$202,000);
- decreased scientific consulting costs (\$196,000);
- lower external development expenses (\$84,000); and
- other net decreases in research spending (\$3,000).

Product costs for MuGard in the United States were \$201,000 for the first nine months of 2012 as compared to \$107,000 for the same period in 2011, an increase of \$94,000.

Total selling, general and administrative expenses were \$4,491,000 for the first nine months of 2012, an increase of \$69,000 compared to the same period in 2011 of \$4,422,000. The increase in expenses was due primarily to the following:

- increased MuGard product selling expenses (\$1,060,000);
- increased salary and related costs (\$99,000);
- increased net other general and administrative expenses (\$10,000);
- decreased general business consulting expenses due to the higher use of outside consultants in 2011 (\$842,000) versus the same period in 2012;
- decreased stock compensation expense due to lower expense of option grants for selling, general and administrative employees and directors (\$258,000); and

Depreciation and amortization was \$91,000 for the first nine months of 2012 as compared to \$176,000 for 2011, a decrease of \$85,000.

Total operating expenses for the first nine months of 2012 were \$6,495,000 as compared to total operating expenses of \$7,527,000 for 2011, a decrease of \$1,032,000 for the reasons listed above.

Interest and miscellaneous income was \$112,000 for the first nine months of 2012 as compared to \$1,291,000 for 2011, a decrease of \$1,179,000. Miscellaneous income was higher in 2011 due to negotiated payables and write-offs of other accounts payable that occurred in 2011.

Interest and other expense was \$524,000 for the first nine months of 2012 as compared to \$760,000 in 2011, a decrease of \$236,000. The decrease in interest and other expense was due to the repayment in full of the secured promissory note of \$2.75 million plus accrued interest.

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

We recorded a gain related to warrants classified as derivative liabilities of \$1,236,000 for the first nine months of 2012 as compared to \$3,312,000 for the same period of 2011. We recorded a derivative for warrants in 2009 when the fair value of the warrants that were issued with our Series A Convertible Preferred Stock were reclassified from equity per the requirements of accounting guidance as a result of the repricing feature.

We recorded a loss for the derivative liability related to preferred stock of \$25,770,000 for the first nine months of 2012 and a loss of \$470,000 for the same period of 2011. We recorded a derivative in 2010 per the requirements of accounting guidance due to the possibility of repricing our Series A Convertible Preferred Stock if we sold our common stock at a price below the original conversion price.

Preferred stock dividends of \$1,323,000 were accrued for the first nine months of 2012 and \$1,327,000 for 2011, a decrease of \$4,000.

Net loss allocable to common stockholders for the first nine months of 2012 was \$31,682,000, or a \$1.31 basic and diluted loss per common share, compared with net loss of \$4,140,000, or a \$0.21 basic and diluted loss per common share for the same period in 2011, an increased loss of \$27,542,000.

### **Critical Accounting Policies and Estimates relating to MuGard**

#### Product sales and allowances

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

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

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

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

(in thousands)	Three months ended March 31, 2012	Three months ended June 30, 2012	Three months ended September 30, 2012	Nine months ended September 30, 2012
Gross sales	\$ 577	\$ 712	\$ 877	\$ 2,166
Cash discounts	5	13	7	25
Contract discounts	18	84	89	191
	<u>\$ 554</u>	<u>\$ 615</u>	<u>\$ 781</u>	<u>\$ 1,950</u>

	Three months ended March 31, 2011	Three months ended June 30, 2011	Three months ended September 30, 2011	Nine months ended September 30, 2011
Gross sales	\$ 13	\$ 43	\$ 82	\$ 138
Cash discounts	-	1	-	1
Contract discounts	-	-	-	-
	<u>\$ 13</u>	<u>\$ 42</u>	<u>\$ 82</u>	<u>\$ 137</u>

#### Cost of product sales

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

#### Selling, general and administrative expense

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

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

Not applicable.

### **ITEM 4. CONTROLS AND PROCEDURES**

Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2012. Based on this evaluation, our CEO and CFO concluded that, as of September 30, 2012, 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 (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) previously disclosed and discussed below.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. 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, 2011 that there is a material weakness in our internal control over financial reporting. A material weakness is a control 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 identified in our Annual Report on Form 10-K for the year ended December 31, 2011 relates to the monitoring and review of work performed by our CFO 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 performed solely by our CFO. 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.

As of the date of this Quarterly 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, as such, 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.

In order to mitigate this material weakness to the fullest extent possible, all financial statements will be reviewed for reasonableness by the Chief Executive Officer as well as the Chairman of the Audit Committee for reasonableness. All unexpected results will be investigated. At any time, if it appears that any control can be implemented to continue to mitigate such weaknesses, it will be immediately implemented. As soon as our finances allow, we plan to 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, 2012 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.**

On June 8, 2012, Alan W. Schmidt, a former shareholder of Genaera Corporation (“Genaera”) and unitholder of the Genaera Liquidating Trust (the “Trust”), filed a putative class action in the U.S. District Court for the Eastern District of Pennsylvania (Docket Number 2:12-cv-03265-BMS) against Access Pharmaceuticals, Inc., MacroChem Corporation, Jeffrey Davis, Steve Rouhandeh, Mark Alvino (the “Access Defendants”) and twenty-five other individuals and entities allegedly related to Genaera and/or the Trust. Schmidt claims that the Access Defendants aided and abetted alleged breaches of fiduciary duties by Genaera’s directors and the Trust in connection with the development of Pexiganan, a drug that Genaera licensed to MacroChem Corporation in 2007. Schmidt generally asserts that the Genaera directors and the Trust failed to obtain appropriate value for Pexiganan, and that the Access Defendants aided and abetted the Genaera directors and the Trust in connection with their performance and termination of the Pexiganan license. Schmidt seeks unspecified money damages. The case is in the preliminary stages. The Company believes the claims against the Access Defendants are without merit and intends to defend the matter vigorously.

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.**

None.

**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, there must either be an effective registration statement covering the resale of the dividend 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, 2012, dividends payable in the aggregate amount of \$8,062,000.

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, 2012, the SEC 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, we have accrued as of September 30, 2012, \$857,000 in liquidated damages. A registration statement filed by us relating to a portion of such securities was declared effective on November 13, 2008.

**ITEM 4. MINE SAFETY DISCLOSURES.**

None.

**ITEM 5. OTHER INFORMATION.**

None.

**ITEM 6. EXHIBITS.**

Exhibits:

- 31.1 Certification of Chief Executive Officer of Access Pharmaceuticals, Inc. filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of Chief Financial Officer of Access Pharmaceuticals, Inc. filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1\* Certification of Chief Executive Officer of Access Pharmaceuticals, Inc. filed pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2\* Certification of Chief Financial Officer of Access Pharmaceuticals, Inc. filed pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
- 101.INS XBRL Instance Document\*\*
- 101.SCH XBRL Taxonomy Schema\*\*
- 101.CAL XBRL Taxonomy Calculation Linkbase Document\*\*
- 101.DEF XBRL Taxonomy Definition Linkbase Document\*\*
- 101.LAB XBRL Taxonomy Label Linkbase Document\*\*
- 101.PRE XBRL Taxonomy Presentation Linkbase Document\*\*

\* 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. Such certification will not be deemed to be 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.

\*\* These exhibits are interactive data files and are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability under these sections.



**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 14, 2012

By: /s/ Jeffrey B. Davis  
Jeffrey B. Davis  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 14, 2012

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Balance Sheets

	September 30, 2012 (unaudited)	December 31, 2011
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 106,000	\$ 2,460,000
Receivables	481,000	333,000
Inventory	236,000	151,000
Restricted cash	-	330,000
Prepaid expenses and other current assets	28,000	39,000
Total current assets	851,000	3,313,000
Property and equipment, net	46,000	51,000
Patents, net	291,000	362,000
Other assets	46,000	59,000
Total assets	\$ 1,234,000	\$ 3,785,000
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities		
Accounts payable	\$ 2,347,000	\$ 1,713,000
Accrued expenses	857,000	857,000
Dividends payable	2,765,000	6,487,000
Accrued interest payable	19,000	98,000
Debt	2,750,000	2,750,000
Current portion of deferred revenue	248,000	285,000
Total current liabilities	8,986,000	12,190,000
Dividends payable to be converted to equity	5,297,000	-
Derivative liability - warrants	271,000	1,507,000
Derivative liability - preferred stock	30,200,000	4,430,000
Long-term deferred revenue	2,768,000	3,264,000
Total liabilities	47,522,000	21,391,000
Commitments and contingencies		
Stockholders' deficit		
Convertible Series A preferred stock - \$.01 par value; authorized 2,000,000 shares; 2,938.3617 shares issued at September 30, 2012 and 2,938.3617 shares issued at December 31, 2011	-	-
Common stock - \$.01 par value; authorized 130,000,000 shares; issued, 24,182,153 at September 30, 2012 and 23,890,787 at December 31, 2011	242,000	239,000
Additional paid-in capital	240,597,000	237,600,000
Treasury stock, at cost – 163 shares	(4,000)	(4,000)
Accumulated deficit	(287,123,000)	(255,441,000)
Total stockholders' deficit	(46,288,000)	(17,606,000)
Total liabilities and stockholders' deficit	\$ 1,234,000	\$ 3,785,000

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Operations  
(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Revenues				
Product sales	\$ 781,000	\$ 82,000	\$ 1,950,000	\$ 137,000
License revenues	62,000	936,000	1,384,000	1,110,000
Royalties	28,000	23,000	64,000	64,000
Sponsored research and development	-	-	-	30,000
Total revenues	871,000	1,041,000	3,398,000	1,341,000
Expenses				
Research and development	308,000	906,000	1,712,000	2,822,000
Product costs	79,000	61,000	201,000	107,000
Selling, general and administrative	1,422,000	1,802,000	4,491,000	4,422,000
Depreciation and amortization	18,000	56,000	91,000	176,000
Total expenses	1,827,000	2,825,000	6,495,000	7,527,000
Loss from operations	(956,000)	(1,784,000)	(3,097,000)	(6,186,000)
Interest and miscellaneous income	111,000	1,283,000	112,000	1,291,000
Interest and other expense	(186,000)	(237,000)	(524,000)	(760,000)
Warrant extension expense	-	-	(2,316,000)	-
Gain on change in fair value of derivative - warrants	64,000	1,138,000	1,236,000	3,312,000
Loss on change in fair value of derivative - preferred stock	(13,900,000)	(50,000)	(25,770,000)	(470,000)
	(13,911,000)	2,134,000	(27,262,000)	3,373,000
Net income (loss)	(14,867,000)	350,000	(30,359,000)	(2,813,000)
Less preferred stock dividends	444,000	447,000	1,323,000	1,327,000
Net loss allocable to common stockholders	\$ (15,311,000)	\$ (97,000)	\$ (31,682,000)	\$ (4,140,000)
Basic/diluted net loss per common share				
Net loss allocable to common stockholders	\$ (0.63)	\$ (0.00)	\$ (1.31)	\$ (0.21)
Weighted average basic and diluted common shares outstanding	24,173,705	19,503,383	24,135,585	19,378,579

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Stockholders' Deficit  
(unaudited)

	Common Stock		Preferred Stock		Additional paid-in capital	Treasury stock	Accumulated deficit
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance December 31, 2011	23,891,000	\$ 239,000	2,938.3617	\$ -	\$ 237,600,000	\$ (4,000)	\$ (255,441,000)
Restricted common stock issued for services	15,000	-	-	-	21,000	-	-
Common stock issued for services	6,000	-	-	-	9,000	-	-
Common stock issued to directors and employees	222,000	2,000	-	-	300,000	-	-
Common stock issued for preferred dividends	11,000	-	-	-	13,000	-	-
Stock option compensation expense	-	-	-	-	114,000	-	-
Warrant extension expense	-	-	-	-	2,316,000	-	-
Preferred dividends	-	-	-	-	-	-	(440,000)
Net loss	-	-	-	-	-	-	(4,892,000)
Balance at March 31, 2012	24,145,000	\$ 241,000	2,938.3617	\$ -	\$ 240,373,000	\$ (4,000)	\$ (260,773,000)
Restricted common stock issued for services	5,000	-	-	-	6,000	-	-
Common stock issued for services	7,000	-	-	-	6,000	-	-
Common stock issued for preferred dividends	7,000	1,000	-	-	8,000	-	-
Stock option compensation expense	-	-	-	-	108,000	-	-
Preferred dividends	-	-	-	-	-	-	(439,000)
Net loss	-	-	-	-	-	-	(10,600,000)
Balance at June 30, 2012	24,164,000	\$ 242,000	2,938.3617	\$ -	\$ 240,501,000	\$ (4,000)	\$ (271,812,000)
Common stock issued for services	18,000	-	-	-	11,000	-	-
Stock option compensation expense	-	-	-	-	85,000	-	-
Preferred dividends	-	-	-	-	-	-	(444,000)
Net loss	-	-	-	-	-	-	(14,867,000)
Balance at September 30, 2012	<u>24,182,000</u>	<u>\$ 242,000</u>	<u>2,938.3617</u>	<u>\$ -</u>	<u>\$ 240,597,000</u>	<u>\$ (4,000)</u>	<u>\$ (287,123,000)</u>

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Cash Flows  
(unaudited)

	Nine Months ended September 30,	
	2012	2011
Cash flows from operating activities:		
Net loss	\$ (30,359,000)	\$ (2,813,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Gain on change in fair value of derivative - warrants	(1,236,000)	(3,312,000)
Loss on change in fair value of derivative - preferred stock	25,770,000	470,000
Warrant extension expense	2,316,000	-
Gain on write-off and negotiated accounts payable	-	(1,282,000)
Depreciation and amortization	91,000	176,000
Stock option compensation expense	307,000	767,000
Stock issued to directors and employees	302,000	-
Stock issued for services	53,000	700,000
Change in operating assets and liabilities:		
Receivables	(148,000)	899,000
Inventory	(85,000)	(192,000)
Prepaid expenses and other current assets	11,000	43,000
Restricted cash	330,000	-
Other assets	13,000	(20,000)
Accounts payable and accrued expenses	634,000	(73,000)
Dividends payable	274,000	197,000
Accrued interest payable	(79,000)	(96,000)
Deferred revenue	(533,000)	(1,109,000)
Net cash used in operating activities	(2,339,000)	(5,645,000)
Cash flows from investing activities:		
Capital expenditures	(15,000)	(40,000)
Net cash used in investing activities	(15,000)	(40,000)
Net decrease in cash and cash equivalents	(2,354,000)	(5,685,000)
Cash and cash equivalents at beginning of period	2,460,000	7,033,000
Cash and cash equivalents at end of period	\$ 106,000	\$ 1,348,000
<i>Supplemental cash flow information:</i>		
Cash paid for interest	\$ 330,000	\$ 660,000
<i>Supplemental disclosure of noncash transactions:</i>		
Shares issued for dividends on preferred stock	22,000	1,000
Preferred stock dividends in dividends payable	\$ 1,323,000	\$ 1,327,000

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

## Access Pharmaceuticals, Inc. and Subsidiaries

### Notes to Condensed Consolidated Financial Statements Three and Nine Months Ended September 30, 2012 and 2011 (unaudited)

Access Pharmaceuticals, Inc. (together with our subsidiaries, “We”, “Access” or the “Company”) is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical and medical device products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies.

#### **(1) Interim Financial Statements**

The condensed consolidated balance sheet as of September 30, 2012, the condensed consolidated statements of operations for the three and nine months ended September 30, 2012 and 2011, the condensed consolidated statements of stockholders’ deficit for the three and nine months ended September 30, 2012, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2012 and 2011, were prepared by management without audit. In the opinion of management, all adjustments, consisting only of normal recurring adjustments, except as otherwise disclosed, necessary for the fair presentation of the financial position, results of operations, and changes in financial position for such periods, have been made.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America have been condensed or omitted. It is suggested that these interim financial statements be read in conjunction with the consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2011. The results of operations for the period ended September 30, 2012 are not necessarily indicative of the operating results which may be expected for a full year. The condensed consolidated balance sheet as of December 31, 2011 contains financial information taken from the audited Access financial statements as of that date.

The report of our independent registered public accounting firm for the fiscal year ended December 31, 2011, contained a fourth explanatory paragraph to reflect its significant doubt about our ability to continue as a going concern as a result of our history of losses and our liquidity position, as discussed therein and in this Quarterly Report on Form 10-Q. We expect that our capital resources, revenues from MuGard sales and expected receipts due under our license agreements will be adequate to fund our current level of operations into the fourth quarter of 2013. 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.

Certain reclassifications to the consolidated financial statements for all periods presented have been made to conform to the September 30, 2012 presentation.

## (2) Intangible Assets

Intangible assets consist of the following (in thousands):

	September 30, 2012		December 31, 2011	
	Gross carrying value	Accumulated amortization	Gross carrying value	Accumulated Amortization
Amortizable intangible assets				
Patents	\$ 2,624	\$ 2,333	\$ 2,624	\$ 2,262

Amortization expense related to intangible assets totaled \$11,000 and \$71,000 for each of the three and nine months ended September 30, 2012 and totaled \$53,000 and \$159,000 for each of the three and nine months ended September 30, 2011. The aggregate estimated amortization expense for intangible assets remaining as of September 30, 2012 is as follows (in thousands):

2012	\$ 11
2013	44
2014	44
2015	44
2016	44
over 5 years	104
Total	<u>\$ 291</u>

## (3) Note Payable

As of September 30, 2012, we had one secured note outstanding in the principal amount of \$2,750,000. The note was due on September 13, 2012. The note was secured by all assets of the company. See Note 8. Subsequent Events.

## (4) Liquidity

The Company generated net loss allocable to common stockholders of \$31,682,000 for the nine months ended September 30, 2012 and a loss of \$4,306,000 for the year ended December 31, 2011. At September 30, 2012, our working capital deficit was \$8,135,000. As of September 30, 2012, we had one secured note outstanding in the principal amount of \$2,750,000. The note was due on September 13, 2012 and paid in full on November 2, 2012. See Note 8. Subsequent Events. Management believes that our current cash, revenues from MuGard sales and expected license fees should fund our expected burn rate into the 4th quarter of 2013. We will require additional funds to continue operations. These funds are expected to come from the future sales of equity and/or license agreements. If we are unable to obtain adequate capital funding in the future or enter into future license agreements for our products, we may not be able to continue as a going concern, which would have an adverse effect on our business and operations, and investors' investment in us may decline.

## (5) Fair Value of Financial Instruments

The carrying value of cash equivalents, receivables, accounts payable and accruals approximate fair value due to the short maturity of these items. The carrying value of the secured debt is at book value which does not bear a market rate of interest. Management believes based on its current financial position that it could not obtain comparable amounts of third party financing, and as such cannot estimate the fair value of the secured debt. None of these instruments are held for trading purposes.

Effective January 1, 2008, we adopted fair value measurement guidance issued by the FASB related to financial assets and liabilities which define fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. This guidance establishes a three-level fair value hierarchy that prioritizes the inputs used to measure fair value. The hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets and liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

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

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

Financial assets and liabilities measured at fair value on a recurring basis as of September 30, 2012 and December 31, 2011 are summarized below:

(in thousands)

Description	As of September 30, 2012	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability- warrants	\$ 271	\$ -	\$ 271	\$ -	\$ 1,236
preferred stock	\$ 30,200	\$ -	\$ -	\$ 30,200	\$ (25,770)

(in thousands)

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



In order to calculate the Level 3 Derivative liability - preferred stock, we used the Monte Carlo simulation to estimate future stock prices. The use of valuation techniques requires the Company to make various key assumptions for inputs into the model, including assumptions about the expected future volatility of the price of the Company's stock. In estimating the fair value at September 30, 2012 and December 31, 2011, we based our selected volatility on the one-year historic volatility of the Company's stock as we believe this is most representative of the expected volatility in the near future for the Company.

#### (6) Stock Based Compensation

For the three and nine months ended September 30, 2012, we recognized stock-based compensation expense of \$85,000 and \$307,000, respectively. For the three and nine months ended September 30, 2011 we recognized stock-based compensation expense of \$344,000 and \$767,000, respectively.

The following table summarizes stock-based compensation for the three and nine months ended September 30, 2012 and 2011:

	Three months ended September 30,		Nine months ended September 30,	
	2012	2011	2012	2011
Research and development	\$ 9,000	\$ 103,000	\$ 83,000	\$ 282,000
Selling, general and administrative	76,000	241,000	224,000	485,000
Stock-based compensation expense included in operating expense	\$ 85,000	\$ 344,000	\$ 307,000	\$ 767,000

For the three and nine months ended September 30, 2012 we granted 0 and 510,000 stock options, respectively. For the three and nine months ended September 30, 2011 we granted 0 and 575,000 stock options, respectively.

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

	9/30/12		9/30/11	
Expected life(b)	5.5 yrs		6.04 yrs	
Risk free interest rate	0.6	%	2.3	%
Expected volatility(a)	96	%	123	%
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.  
(b) Based on the simplified method.

#### (7) Litigation

On June 8, 2012, Alan W. Schmidt, a former shareholder of Genaera Corporation ("Genaera") and unitholder of the Genaera Liquidating Trust (the "Trust"), filed a putative class action in the U.S. District Court for the Eastern District of Pennsylvania (Docket Number 2:12-cv-03265-BMS) against Access Pharmaceuticals, Inc., MacroChem Corporation, Jeffrey Davis, Steve Rouhandeh, Mark Alvino (the "Access Defendants") and twenty-five other individuals and entities allegedly related to Genaera and/or the Trust. Schmidt claims that the Access Defendants aided and abetted alleged breaches of fiduciary duties by Genaera's directors and the Trust in connection with the development of Pexiganan, a drug that Genaera licensed to MacroChem Corporation in 2007. Schmidt generally asserts that the Genaera directors and the Trust failed to obtain appropriate value for Pexiganan, and that the Access Defendants aided and abetted the Genaera directors and the Trust in connection with their performance and termination of the Pexiganan license. Schmidt seeks unspecified money damages. The case is in the preliminary stages. The Company believes the claims against the Access Defendants are without merit and intends to defend the matter vigorously.

## **(8) Subsequent Events**

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

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



**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 14, 2012

/s/ Jeffrey B. Davis

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 14, 2012

/s/ Stephen B. Thompson  
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, 2012, 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 14th day of November, 2012.

/s/ Jeffrey B. Davis

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, 2012, 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 14th day of November, 2012.

/s/ Stephen B. Thompson  
Stephen B. Thompson  
Chief Finance Officer