# UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, DC 20549

**FORM 10-Q** (Mark One)  $\overline{\mathbf{V}}$ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES **EXCHANGE ACT OF 1934** For the quarterly period ended June 30, 2012 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** 83-0221517 (State or other jurisdiction of (I.R.S. Employer I.D. No.) incorporation or organization) 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 ☑ 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 **☑** 

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

(Do not check if a smaller reporting company)

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

Common shares, \$0.01 par value - 24,172,877 shares issued and outstanding as of August 14, 2012

Series A Convertible preferred stock , \$0.01 par value - 2,938.3617 shares issued and outstanding as of August 14, 2012 and convertible into 20,264,551 shares of common stock

## ACCESS PHARMACEUTICALS, INC.

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### 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 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, two products at Phase 2 of clinical development and several products in pre-clinical development. The success of our low priority clinical and pre-clinical programs will be dependent on our ability to enter into collaboration arrangements. Certain of our development programs are dependent upon our ability to secure approved funding for such projects.

#### **Marketed Product**

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

### **Product Candidates**

- · Our lead development candidate for the treatment of cancer is ProLindac<sup>TM</sup>, 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.
- · Thiarabine, or 4-thio Ara-C, is a next generation nucleoside analog licensed from Southern Research Institute. Previously named SR9025 and OSI-7836, the compound has been in two Phase 1/2 solid tumor human clinical trials and was shown to have anti-tumor activity. We are working with leukemia and lymphoma specialists at MD Anderson Cancer Center in Houston and have initiated additional Phase 2 clinical trials in adult AML, ALL and other indications. We are currently evaluating data from the trials to decide on how to proceed.
- · CobOral<sup>®</sup> is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We are currently developing a product for the oral delivery of insulin, and have conducted sponsored development of a product for oral delivery of a number of peptides and RNAi therapeutics. We have signed agreements with several companies regarding the sponsored development of CobOral drug delivery formulations of proprietary and non-proprietary actives.

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

### **Products and Product Candidates**

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

## **Access Drug Portfolio**

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

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

## RECENT EVENTS

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.

<sup>(2)</sup> Licensed from the School of Pharmacy, The University of London.

<sup>(3)</sup> Licensed from Southern Research Institute of Birmingham, Alabama.

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. Manufacturing will commence shortly in the United States to meet the demand created by Jian An, Rhei's sales and marketing partner in China.

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

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

## 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 six months ended June 30, 2012. As of June 30, 2012, our cash and cash equivalents were \$588,000 and our net cash burn rate for the six months ended June 30, 2012, was approximately \$263,000 per month. As of June 30, 2012, our working capital deficit was \$12,015,000. Our working capital deficit at June 30, 2012 represented an increase of \$3,138,000 as compared to our working capital deficit as of December 31, 2011 of \$8,877,000. The increase in the working capital deficit at June 30, 2012 reflects six months of net operating costs. As of June 30, 2012, we had one secured promissory note outstanding in the principal amount of \$2.75 million that is due on September 13, 2012.

As of August 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 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 June 30, 2012 of \$271,812,000. We expect that our capital resources, revenues from MuGard sales and expected receipts due under our license agreements will be adequate to fund our current level of operations into the third quarter of 2012. We have one secured promissory note outstanding in the principal amount of \$2.75 million that is due on September 13, 2012. However, we do not have the funds on hand to pay this secured promissory note. 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 immediately. 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.

## SECOND QUARTER 2012 COMPARED TO SECOND QUARTER 2011

Our licensing revenue for the second quarter of 2012 was \$60,000 as compared to \$87,000 for the same period of 2011, a decrease of \$27,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

Product sales of MuGard in the United States totaled \$615,000 for the second quarter of 2012 as compared with \$42,000 for the same period of 2011, an increase of \$573,000.

We recorded royalty revenue for MuGard in Europe of \$15,000 for second quarter of 2012 as compared to \$21,000 for the same period of 2011, a decrease of \$6,000.

Total research and development spending for the second quarter of 2012 was \$654,000, as compared to \$903,000 for the same period of 2011, a decrease of \$249,000. The decrease in expenses was primarily due to:

- · decreased clinical development with trials for ProLindac, MuGard and Thiarabine (\$184,000);
- · decreased stock compensation expense for lower expense of option grants for research and development employees (\$60,000);
- · decreased external lab costs for studies (\$40,000);
- · decreased scientific consulting costs (\$27,000);
- · increased salary and related costs (\$42,000); and
- · other net increases in research spending (\$20,000).

Product costs for MuGard in the United States were \$63,000 for the second quarter of 2012 as compared to \$37,000 for the same period in 2011, an increase of \$26,000.

Total selling, general and administrative expenses were \$1,406,000 for the second quarter of 2012, an increase of \$2,000 compared to the same period in 2011 of \$1,404,000. The decrease in expenses was due primarily to the following:

- · decreased general business consulting expenses due to less use of outside consultants in 2012 (\$207,000) versus the same period in 2011;
- · decreased stock compensation expense for lower expense of option grants for selling, general and administrative employees (\$75,000);
- · decreased net other general and administrative expenses (\$4,000); and
- · increased MuGard product selling expenses (\$288,000).

Depreciation and amortization was \$19,000 for the second quarter of 2012 as compared to \$59,000 for the same period in 2011, a decrease of \$40,000, due to assets being fully depreciated.

Total operating expenses for the second quarter of 2012 year were \$2,142,000 as compared to total operating expenses of \$2,403,000 for the same period of 2011, a decrease of \$261,000 for the reasons listed above.

There was no interest and miscellaneous income for the second quarter of 2012 as compared to \$3,000 for the same period of 2011, a decrease of \$3,000.

Interest and other expense was \$169,000 for the second quarter of 2012 as compared to \$356,000 in the same period of 2011, a decrease of \$187,000. 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 \$431,000 for the second quarter of 2012 as compared to \$939,000 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 \$9,410,000 for the second quarter of 2012 and a gain of \$403,000 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 \$439,000 were accrued for the second quarter of 2012 and \$442,000 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 second quarter of 2012 was \$11,039,000, or a \$0.46 basic and diluted loss per common share, compared with a net loss of \$1,706,000, or a \$0.09 basic and diluted loss per common share, for the same period in 2011, an increased loss of \$9,333,000.

## SIX MONTHS ENDED JUNE 30, 2012 COMPARED TO SIX MONTHS ENDED JUNE 30, 2011

Our licensing revenue for the first six months of 2012 was \$1,322,000 as compared to \$174,000 for 2011, an increase of \$1,148,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements. In the first quarter of 2012, we finalized the negotiations for the termination of the license from our European partner for MuGard and recognized all of the previously received license fees (\$706,000) that were recorded in deferred revenue and a \$500,000 termination fee.

Product sales of MuGard in the United States totaled \$1,169,000 for the first six months of 2012 as compared to \$55,000 for the same period of 2011, an increase of \$1,114,000.

We recorded royalty revenue for MuGard in Europe of \$36,000 for the first six months of 2012 as compared to \$41,000 for 2011, a decrease of \$5,000.

Sponsored research and development revenues were \$30,000 for the first six 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 six months of 2012 was \$1,404,000, as compared to \$1,916,000 for 2011, a decrease of \$512,000. The decrease in expenses was primarily due to:

- · decreased clinical development with trials for ProLindac, MuGard and Thiarabine (\$329,000);
- · decreased scientific consulting costs (\$129,000);
- · decreased stock compensation expense for lower expense of option grants for research and development employees (\$104,000);
- · lower external development expenses (\$100,000);
- · other net decreases in research spending (\$24,000); and
- · increased salary and related costs (\$174,000);

Product costs for MuGard in the United States were \$122,000 for the first six months of 2012 as compared to \$46,000 for the same period in 2011, an increase of \$76,000.

Total selling, general and administrative expenses were \$3,069,000 for the first six months of 2012, an increase of \$449,000 compared to the same period in 2011 of \$2,620,000. The increase in expenses was due primarily to the following:

- · increased MuGard product selling expenses (\$699,000);
- · increased salary and related costs (\$239,000);
- · increased professional expenses (\$60,000);
- · decreased general business consulting expenses due to the higher use of outside consultants in 2012 (\$447,000) versus the same period in 2011;
- · decreased stock compensation expense due to higher expense of option grants for selling, general and administrative employees and directors (\$97,000); and
- · decreased net other general and administrative expenses (\$5,000).

Depreciation and amortization was \$73,000 for the first six months of 2012 as compared to \$120,000 for 2011, a decrease of \$47,000.

Total operating expenses for the first six months of 2012 were \$4,668,000 as compared to total operating expenses of \$4,702,000 for 2011, a decrease of \$34,000 for the reasons listed above.

Interest and miscellaneous income was \$1,000 for the first six months of 2012 as compared to \$8,000 for 2011, a decrease of \$7,000.

Interest and other expense was \$338,000 for the first six months of 2012 as compared to \$523,000 in 2011, a decrease of \$185,000. The decrease in interest and other expense was due to a pay down of the secured promissory note of \$2.75 million.

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

We recorded a gain related to warrants classified as derivative liabilities of \$1,172,000 for the first six months of 2012 as compared to \$2,174,000 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 \$11,870,000 for the first six months of 2012 and a loss of \$420,000 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 \$879,000 were accrued for the first six months of 2012 and \$880,000 for 2011, a decrease of \$1,000.

Net loss allocable to common stockholders for the first six months of 2012 was \$16,371,000, or a \$0.68 basic and diluted loss per common share, compared with net loss of \$4,043,000, or a \$0.21 basic and diluted loss per common share for the same period in 2011, an increased loss of \$12,328,000.

## 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.

|                            | Three          |     | Three               |                    | Six                 |                    |
|----------------------------|----------------|-----|---------------------|--------------------|---------------------|--------------------|
|                            | months         |     | Months              |                    | Months              |                    |
|                            | ended          |     | ended               |                    | ended               |                    |
|                            | March          |     | June                |                    | June                |                    |
|                            | 31,            |     | 30,                 |                    | 30,                 |                    |
| (in thousands)             | 2012           |     | 2012                |                    | 2012                |                    |
| Gross sales                | \$             | 577 | \$                  | 712                | \$                  | 1,289              |
| Cash discounts             |                | 5   |                     | 13                 |                     | 18                 |
| Contract discounts         |                | 18  |                     | 84                 |                     | 102                |
|                            | \$             | 554 | \$                  | 615                | \$                  | 1,169              |
|                            |                |     |                     |                    |                     |                    |
|                            | Three          |     | Three               |                    | Six                 |                    |
|                            | months         |     | Months              |                    | Months              |                    |
|                            | ended          |     |                     |                    | 1 1                 |                    |
|                            | chaca          |     | ended               |                    | ended               |                    |
|                            | March          |     | June                |                    | ended<br>June       |                    |
|                            |                |     |                     |                    |                     |                    |
| (in thousands)             | March          |     | June                |                    | June                |                    |
| (in thousands) Gross sales | March 31,      | 13  | June<br>30,         | 43                 | June 30,            | 56                 |
|                            | March 31, 2011 | 13  | June<br>30,<br>2011 | 43                 | June<br>30,<br>2011 | 56<br>1            |
| Gross sales                | March 31, 2011 | 13  | June<br>30,<br>2011 | 43                 | June<br>30,<br>2011 | 56<br>1            |
| Gross sales Cash discounts | March 31, 2011 | 13  | June<br>30,<br>2011 | 43<br>1<br>-<br>42 | June<br>30,<br>2011 | 56<br>1<br>-<br>55 |

## 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 June 30, 2012. Based on this evaluation, our CEO and CFO concluded that, as of June 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 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 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 June 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.

We are not currently a party to any legal proceedings that we believe could have a material impact on our financial condition or results of operations.

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

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

## 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 June 30, 2012, dividends payable in the aggregate amount of \$7,517,000.

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 June 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 June 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. [REMOVED AND RESERVED.]

### ITEM 5. OTHER INFORMATION.

None.

### ITEM 6. EXHIBITS.

| $\mathbf{E}\mathbf{x}$ | hit | oits | , |
|------------------------|-----|------|---|
|                        |     |      |   |

31.1

|      | 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 |

Certification of Chief Executive Officer of Access Pharmaceuticals, Inc. filed pursuant to Section 302 of

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\*\*

<sup>\*</sup> 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.

<sup>\*\*</sup> 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: August 14, 2012 By: /s/ Jeffrey B. Davis

Jeffrey B. Davis

Chief Executive Officer (Principal Executive Officer)

Date: August 14, 2012 By: /s/ Stephen B. Thompson

Stephen B. Thompson

Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)

## Condensed Consolidated Balance Sheets

|   | June 30, 2012 | December 31, 2011 |
|---|---------------|-------------------|
| ASSETS  | (unaudited)   |                   |
| Current assets  |               |                   |
| Cash and cash equivalents                               | \$ 588,000    | \$ 2,460,000      |
| Receivables   | 788,000       | 333,000           |
| Inventory   | 281,000       | 151,000           |
| Restricted cash   | 330,000       | 330,000           |
| Prepaid expenses and other current assets               | 44,000        | 39,000            |
| Total current assets                                    | 2,031,000     | 3,313,000         |
| Property and equipment, net                             | 53,000        | 51,000            |
| Patents, net  | 302,000       | 362,000           |
| Other assets  | 51,000        | 59,000            |
| Total assets  | \$ 2,437,000  | \$ 3,785,000      |
| LIABILITIES AND STOCKHOLDERS' DEFICIT                   |               |                   |
| Current liabilities                                     |               |                   |
| Accounts payable  | \$ 2,410,000  | \$ 1,713,000      |
| Accrued expenses  | 857,000       | 857,000           |
| Dividends payable                                       | 7,517,000     | 6,487,000         |
| Accrued interest payable                                | 264,000       | 98,000            |
| Debt  | 2,750,000     | 2,750,000         |
| Current portion of deferred revenue                     | 248,000       | 285,000           |
| Total current liabilities                               | 14,046,000    | 12,190,000        |
| Derivative liability - warrants                         | 335,000       | 1,507,000         |
| Derivative liability - preferred stock                  | 16,300,000    | 4,430,000         |
| Long-term deferred revenue                              | 2,829,000     | 3,264,000         |
| Total liabilities                                       | 33,510,000    | 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 June 30,  | -             | -                 |
| 2012 and 2,938.3617 shares issued at December 31, 2011  |               |                   |
| Common stock - \$.01 par value; authorized 130,000,000  |               |                   |
| shares;   | 242,000       | 239,000           |
| issued, 24,163,918 at June 30, 2012 and 23,890,787 at   | 240,501,000   | 237,600,000       |
| December 31, 2011                                       | (4,000)       | (4,000)           |
| Additional paid-in capital                              | (271,812,000) | (255,441,000)     |
| Treasury stock, at cost – 163 shares                    |               |                   |
| Accumulated deficit                                     |               |                   |
| Total stockholders' deficit                             | (31,073,000)  | (17,606,000)      |
| Total liabilities and stockholders' deficit             | \$ 2,437,000  | \$ 3,785,000      |
|   |               |                   |

## Condensed Consolidated Statements of Operations (unaudited)

|   | Three m       | onths ended          | Six months ended |               |  |  |
|---|---------------|----------------------|------------------|---------------|--|--|
|   | Jui           | ne 30,               | June 30,         |               |  |  |
|   | 2012 2011     |                      | 2012             | 2011          |  |  |
| Revenues                                  |               |                      |                  |               |  |  |
| License revenues                          | \$ 60,000     | \$ 87,000            | \$ 1,322,000     | \$ 174,000    |  |  |
| Product sales                             | 615,000       | 42,000               | 1,169,000        | 55,000        |  |  |
| Royalties                                 | 15,000        | 21,000               | 36,000           | 41,000        |  |  |
| Sponsored research and development        | -             | -                    | -                | 30,000        |  |  |
| Total revenues                            | 690,000       | 150,000              | 2,527,000        | 300,000       |  |  |
|   |               |                      |                  |               |  |  |
| Expenses                                  |               |                      |                  |               |  |  |
| Research and development                  | 654,000       | 903,000              | 1,404,000        | 1,916,000     |  |  |
| Product costs                             | 63,000        | 37,000               | 122,000          | 46,000        |  |  |
| Selling, general and administrative       | 1,406,000     | 1,404,000            | 3,069,000        | 2,620,000     |  |  |
| Depreciation and amortization             | 19,000        | 59,000               | 73,000           | 120,000       |  |  |
| Total expenses                            | 2,142,000     | 2,403,000            | 4,668,000        | 4,702,000     |  |  |
|   |               |                      |                  |               |  |  |
| Loss from operations                      | (1,452,000    | ) (2,253,000)        | (2,141,000)      | (4,402,000)   |  |  |
|   |               |                      |                  |               |  |  |
| Interest and miscellaneous income         | -             | 3,000                | 1,000            | 8,000         |  |  |
| Interest and other expense                | (169,000      | ) (356,000)          | (338,000)        | (523,000)     |  |  |
| Warrant extension expense                 | -             | -                    | (2,316,000)      | -             |  |  |
| Gain on change in fair value of           |               |                      |                  |               |  |  |
| derivative - warrants                     | 431,000       | 939,000              | 1,172,000        | 2,174,000     |  |  |
| Gain (loss) on change in fair value of    |               |                      |                  |               |  |  |
| derivative - preferred stock              | (9,410,000    | <u> </u>             | (11,870,000)     | (420,000)     |  |  |
|   | (9,148,000    | 989,000              | (13,351,000)     | 1,239,000     |  |  |
| Net loss                                  | (10,600,000   | ) (1,264,000)        | (15,492,000)     | (3,163,000)   |  |  |
|   |               |                      |                  |               |  |  |
| Less preferred stock dividends            | 439,000       | 442,000              | 879,000          | 880,000       |  |  |
| Net loss allocable to common              |               |                      |                  |               |  |  |
| stockholders                              | \$(11,039,000 | <u>\$(1,706,000)</u> | \$(16,371,000)   | \$(4,043,000) |  |  |
|   |               |                      |                  |               |  |  |
| Basic/diluted net loss per common share   |               |                      |                  |               |  |  |
| Net loss allocable to common stockholders | \$ (0.46)     | ) \$ (0.09)          | \$ (0.68)        | \$ (0.21)     |  |  |
|   |               |                      |                  |               |  |  |
| Weighted average basic and diluted        |               |                      |                  |               |  |  |
| common shares outstanding                 | 24,160,686    | 19,387,906           | 24,116,316       | 19,315,142    |  |  |
| · ·                                       |               |                      |                  |               |  |  |

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

Common Stock

Preferred Stock

| Salance December   31,201  |                   | Ohama      | A            | Characa      | A          | Additional paid-in | Treasury   | Accumulated      |
|--|-------------------|------------|--------------|--------------|------------|--------------------|------------|------------------|
| 31,201   | D.1 D             | Snares     | Amount       | Snares       | Amount     | <u>capitai</u>     | Stock      | deficit          |
| Restricted common stock issued for services 15,000 c 21,000 c 20,000 c 20,0 |                   | 22 801 000 | e 220.000    | 2 028 2617   | ¢.         | e 227.000.000      | ¢ (4,000)  | 0 (255 441 000)  |
| Stock issued for services   15,000   | ,                 | 23,891,000 | \$ 239,000   | 2,938.3017   | \$ -       | \$ 237,000,000     | \$ (4,000) | \$ (233,441,000) |
| Services   15,000  |                   |            |              |              |            |                    |            |                  |
| Common stock issued for services   6,000   0   9,000   0   0   0   0   0   0   0   0   0   |                   | 15,000     |              |              |            | 21 000             |            |                  |
| For services 6,000   6,000   7 |                   | 15,000     |              |              | -          | 21,000             | -          | -                |
| Services   G,000   G   G,000   G   G,000   G   G,000   G   G,000   G   G,000   G   G,000   G   |                   |            |              |              |            |                    |            |                  |
| Common stock issued for  |                   | 6,000      |              |              |            | 0.000              |            |                  |
| to directors and employees 222,000 2,000 - 300,000 - 5 Employees 222,000 2,000 - 300,000 - 5 Employees 222,000 - 300,000 - 5 Employees 222,000 - 5 Employe |                   | 0,000      | -            | -            | -          | 9,000              | -          | -                |
| directors and employees   222,000   2,000     300,000  |                   |            |              |              |            |                    |            |                  |
| employees 222,000 2,000 - 300,000  |                   |            |              |              |            |                    |            |                  |
| Common stock issued for preferred dividends  |                   | 222,000    | 2 000        |              |            | 200,000            |            |                  |
| For preferred dividends  | 1 *               | 222,000    | 2,000        | -            | -          | 300,000            | -          | -                |
| Preferred dividends  |                   |            |              |              |            |                    |            |                  |
| Stock option compensation com   |                   | 11,000     |              |              |            | 13 000             |            |                  |
| Compensation   Expense   Compensation   Expense   Compense   Com   |                   | 11,000     | -            | -            | -          | 13,000             | -          | -                |
| Respense   |                   |            |              |              |            |                    |            |                  |
| Warrant extension expense         -         114,000 capense         -         114,000 capense         -         -         144,000 capense         -         -         2,316,000 capense         -         -         (440,000) capense         -  |                   |            |              |              |            |                    |            |                  |
| Preferred dividends  |                   |            |              |              |            | 114 000            | -          | -                |
| Preferred dividends Net loss  (440,000) Net loss (4892,000) 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  |                   |            | -            |              | -          |                    |            |                  |
| Net loss   |                   |            |              |              | _          |                    |            | (440,000)        |
| 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 6,000 Common stock issued for services 7,000 6,000   |                   | _          |              | _            |            |                    |            | ( , ,            |
| 24,145,000   | _                 |            | <del>_</del> | <del>_</del> | <u> </u>   | <u>-</u>           | <u> </u>   | (4,072,000)      |
| Restricted common stock issued for services 5,000 6,000 Common stock issued for services 7,000 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 (439,000) Net loss (439,000) Balance at June 30,   |                   | 24 145 000 | \$ 241,000   | 2 038 3617   | ¢          | \$ 240,373,000     | \$ (4,000) | \$ (260.773.000) |
| stock issued for services 5,000 6,000  Common stock issued for services 7,000 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 108,000  Preferred dividends (439,000) Net loss (10,600,000)  Balance at June 30,   | 2012              | 24,143,000 | \$ 241,000   | 2,938.3017   | <b>5</b> - | \$ 240,373,000     | \$ (4,000) | \$ (200,773,000) |
| stock issued for services 5,000 6,000  Common stock issued for services 7,000 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 108,000  Preferred dividends (439,000) Net loss (10,600,000)  Balance at June 30,   | Restricted common |            |              |              |            |                    |            |                  |
| services 5,000 6,000 Common stock issued for services 7,000 6,000 6,000 6,000 6,000 6,000 6,000 6,000 6,000  |                   |            |              |              |            |                    |            |                  |
| Common stock issued for services 7,000 6,000 Common stock issued for services 7,000 1,000 6,000 Common stock issued for services 7,000 1,000 8,000 Stock option compensation expense 108,000 Preferred dividends 108,000 (439,000) Net loss (10,600,000) Balance at June 30,   |                   | 5,000      | _            | _            | _          | 6,000              | _          | <u>_</u>         |
| 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,   |                   | 3,000      |              |              |            | 0,000              |            |                  |
| 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,   |                   |            |              |              |            |                    |            |                  |
| Common stock issued for  |                   | 7 000      | _            | _            | _          | 6 000              | _          | _                |
| for preferred dividends 7,000 1,000 8,000 Stock option compensation expense 108,000 (439,000) Net loss (10,600,000) Balance at June 30,  |                   | ,,000      |              |              |            | 0,000              |            |                  |
| 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,         -  |                   |            |              |              |            |                    |            |                  |
| Stock option       compensation       expense     -     -     108,000     -     -       Preferred dividends     -     -     -     -     -     -     (439,000)       Net loss     -     -     -     -     -     -     (10,600,000)       Balance at June 30,  |                   | 7 000      | 1 000        | _            | _          | 8 000              | _          | _                |
| compensation       expense     -     -     108,000     -     -       Preferred dividends     -     -     -     -     -     -     -     -     (439,000)       Net loss     -     -     -     -     -     -     -     (10,600,000)       Balance at June 30,   |                   | ,,         | -,           |              |            | -,                 |            |                  |
| expense - 108,000 - 108,00 | *                 |            |              |              |            |                    |            |                  |
| Preferred dividends (439,000) Net loss (10,600,000) Balance at June 30,  |                   |            | _            |              | _          | 108.000            | _          | _                |
| Net loss (10,600,000) Balance at June 30,  |                   |            | _            |              | _          | -                  | _          | (439,000)        |
| Balance at June 30,  |                   | _          | _            | -            | _          | _                  | _          | ( , ,            |
|  |                   |            |              |              |            |                    |            | ,,)              |
|  |                   | 24,164,000 | \$ 242,000   | 2,938.3617   | \$ -       | \$ 240,501,000     | \$ (4,000) | \$ (271,812,000) |

## Condensed Consolidated Statements of Cash Flows (unaudited)

Six Months ended June 30.

|  |           | Six Months ended June 30,             |          |  |  |  |
|--|-----------|---------------------------------------|----------|--|--|--|
|  |           | 2012                                  | 2011     |  |  |  |
| Cash flows from operating activities:  |           |                                       |          |  |  |  |
| Net loss   | \$        | (15,492,000)                          | \$       | (3,163,000)                                |  |  |
| Adjustments to reconcile net loss to cash used   |           |                                       |          |  |  |  |
| in operating activities:   |           |                                       |          |  |  |  |
| Gain on change in fair value of derivative - warrants  |           | (1,172,000)                           |          | (2,174,000)                                |  |  |
| Loss on change in fair value of derivative - preferred stock   |           | 11,870,000                            |          | 420,000                                    |  |  |
| Warrant extension expense  |           | 2,316,000                             |          | -  |  |  |
| Depreciation and amortization  |           | 73,000                                |          | 120,000                                    |  |  |
| Stock option compensation expense  |           | 222,000                               |          | 423,000                                    |  |  |
| Stock issued to directors and employees  |           | 302,000                               |          | -  |  |  |
| Stock issued for services  |           | 43,000                                |          | 475,000                                    |  |  |
| Change in operating assets and liabilities:  |           |                                       |          |  |  |  |
| Receivables  |           | (455,000)                             |          | 967,000                                    |  |  |
| Inventory  |           | (130,000)                             |          | -  |  |  |
| Prepaid expenses and other current assets  |           | (5,000)                               |          | (5,000)                                    |  |  |
| Other assets   |           | 8,000                                 |          | (24,000)                                   |  |  |
| Accounts payable and accrued expenses  |           | 697,000                               |          | (37,000)                                   |  |  |
| Dividends payable  |           | 172,000                               |          | 124,000                                    |  |  |
| Accrued interest payable   |           | 166,000                               |          | 399,000                                    |  |  |
| Deferred revenue   |           | (472,000)                             |          | (173,000)                                  |  |  |
| Net cash used in operating activities  |           | (1,857,000)                           |          | (2,648,000)                                |  |  |
|  |           | · · · · · · · · · · · · · · · · · · · | -        |  |  |  |
| Cash flows from investing activities:  |           |                                       |          |  |  |  |
| Capital expenditures   |           | (15,000)                              |          | (39,000)                                   |  |  |
| Net cash used in investing activities  |           | (15,000)                              |          | (39,000)                                   |  |  |
| Ç  |           |                                       |          |  |  |  |
| Net decrease in cash and cash equivalents  |           | (1,872,000)                           |          | (2,687,000)                                |  |  |
| Cash and cash equivalents at beginning of period   |           | 2,460,000                             |          | 7,033,000                                  |  |  |
| Cash and cash equivalents at end of period   | \$        | 588,000                               | \$       | 4,346,000                                  |  |  |
| The second secon | <u>*</u>  |                                       | <u> </u> | <i>y-</i> - <i>y</i> - <i>-</i> - <i>y</i> |  |  |
| Supplemental cash flow information:  |           |                                       |          |  |  |  |
| Cash paid for interest   | \$        | _                                     | \$       | _  |  |  |
| Cush pain for thickest   | Ψ         | _                                     | Ψ        |  |  |  |
| Supplemental disclosure of noncash transactions:   |           |                                       |          |  |  |  |
| Shares issued for dividends on preferred stock   |           | 22,000                                |          | 1,000                                      |  |  |
| Preferred stock dividends in dividends payable   | \$        | 879,000                               | \$       | 880,000                                    |  |  |
| 1 rejerred stock dividends in dividends paydote  | $\varphi$ | 0/2,000                               | Ψ        | 000,000                                    |  |  |

Notes to Condensed Consolidated Financial Statements Three and Six Months Ended June 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 June 30, 2012, the condensed consolidated statements of operations for the three and six months ended June 30, 2012 and 2011, the condensed consolidated statements of stockholders' deficit for the three and six months ended June 30, 2012, and the condensed consolidated statements of cash flows for the six months ended June 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 June 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 third quarter of 2012. However, we do not have the funds on hand to pay the secured promissory note. 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 June 30, 2012 presentation.

## (2) Intangible Assets

Intangible assets consist of the following (in thousands):

|                               | June 30, 2012 |       |              |         | December 31, 2011 |             |              |       |  |
|-------------------------------|---------------|-------|--------------|---------|-------------------|-------------|--------------|-------|--|
|                               | Gross         |       |              |         | Gross             | }           |              |       |  |
|                               | carrying      |       | Accumula     | carryin | _                 | Accumulated |              |       |  |
|                               | value         |       | amortization |         | value             |             | Amortization |       |  |
| Amortizable intangible assets |               |       |              |         |                   |             |              |       |  |
| Patents                       | \$            | 2,624 | \$           | 2,322   | \$                | 2,624       | \$           | 2,262 |  |

Amortization expense related to intangible assets totaled \$11,000 and \$60,000 for each of the three and six months ended June 30, 2012 and totaled \$53,000 and \$106,000 for each of the three and six months ended June 30, 2011. The aggregate estimated amortization expense for intangible assets remaining as of June 30, 2012 is as follows (in thousands):

| 2012   | \$<br>22  |
|--------|-----------|
| 2013   | 44        |
| 2014   | 44        |
| 2015   | 44        |
| 2016   | 44        |
| over 5 | 104       |
| years  |           |
|        |           |
| Total  | \$<br>302 |

## (3) Note Payable

As of June 30, 2012, we had one secured note outstanding in the principal amount of \$2,750,000. The note is due on September 13, 2012. The note is secured by all assets of the company.

## (4) Liquidity

The Company generated net loss allocable to common stockholders of \$16,371,000 for the six months ended June 30, 2012 and a loss of \$4,306,000 for the year ended December 31, 2011. At June 30, 2012, our working capital deficit was \$12,015,000. As of June 30, 2012, we had one secured note outstanding in the principal amount of \$2,750,000. The note is due on September 13, 2012. Management believes that our current cash, revenues from MuGard sales and expected license fees should fund our expected burn rate into the third quarter of 2012. We will require additional funds to continue operations. We do not have funds to pay the secured note. 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 June 30, 2012 and December 31, 2011 are summarized below:

| <u>(in thousands)</u> |      |           |         |   |             |              |    |             |
|-----------------------|------|-----------|---------|---|-------------|--------------|----|-------------|
|                       |      | As of     |         |   |             |              | ,  | Total Gains |
| Description           | June | 2012      | Level 1 |   | Level 2     | Level 3      |    | (Losses)    |
| Liabilities:          |      |           |         |   |             |              |    |             |
| Derivative liability- |      |           |         |   |             |              |    |             |
| warrants              | \$   | 335       | \$      | - | \$<br>355   | \$<br>-      | \$ | 1,172       |
| preferred stock       | \$   | 16,300    | \$      | - | \$<br>=     | \$<br>16,300 | \$ | (11,870)    |
|                       |      |           |         |   |             |              |    |             |
| (in thousands)        |      |           |         |   |             |              |    |             |
|                       |      | As of     |         |   |             |              |    |             |
|                       | Dec  | ember 31, |         |   |             |              | ,  | Total Gains |
| Description           |      | 2011      | Level 1 |   | Level 2     | Level 3      |    | (Losses)    |
| Liabilities:          |      |           |         |   |             |              |    |             |
| Derivative liability- |      |           |         |   |             |              |    |             |
| warrants              | \$   | 1,507     | \$      | - | \$<br>1,507 | \$<br>-      | \$ | 3,580       |
| preferred stock       | \$   | 4,430     | \$      | - | \$<br>-     | \$<br>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 June 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 six months ended June 30, 2012, we recognized stock-based compensation expense of \$108,000 and \$222,000, respectively. For the three and six months ended June 30, 2011 we recognized stock-based compensation expense of \$242,000 and \$423,000, respectively.

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

|  | <br>Three months ended June 30, |    |         |    | Six months ended June 30, |    |         |  |
|--|---------------------------------|----|---------|----|---------------------------|----|---------|--|
|  | <br>2012                        |    | 2011    |    | 2012                      |    | 2011    |  |
| Research and development                                       | \$<br>33,000                    | \$ | 92,000  | \$ | 74,000                    | \$ | 179,000 |  |
| Selling, general and administrative                            | 75,000                          |    | 150,000 |    | 148,000                   |    | 244,000 |  |
| Stock-based compensation expense included in operating expense | \$<br>108,000                   | \$ | 242,000 | \$ | 222,000                   | \$ | 423,000 |  |

For the three and six months ended June 30, 2012 we granted 510,000 and 510,000 stock options, respectively. For the three and six months ended June 30, 2011 we granted 475,000 and 575,000 stock options, respectively.

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

|                                    | 6/30/12 | 6/30/11  |     |   |  |
|------------------------------------|---------|----------|-----|---|--|
| Expected life <sup>(b)</sup>       | 5.5 yrs | 6.04 yrs |     |   |  |
| Risk free interest rate            | 0.6     | %        | 2.0 | % |  |
| Expected volatility <sup>(a)</sup> | 96      | %        | 119 | % |  |
| Expected dividend yield            | 0.0     | %        | 0.0 | % |  |

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

<sup>(</sup>b) Based on the simplified method.



### **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;
  - 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: August 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: August 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 June 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 August, 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 June 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 August, 2012.

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