

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 June 30, 2013  
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 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   
(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.

The number of shares outstanding of the registrant's common stock as of August 14, 2013 was 25,432,918 shares. Also outstanding at August 14, 2013 were 2,903.3617 shares of Series A Cumulative Convertible Preferred Stock (the "Series A Preferred Stock") convertible into 58,067,234 shares of common stock and 1,000.0 shares of Series B Cumulative Convertible Preferred Stock (the "Series B Preferred Stock") convertible into 20,000,000 shares of common stock.

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**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, revenues from sales and license agreements, our expectation that our capital resources, sales revenues and receipts will be adequate to fund our current level of operations into the first quarter of 2014, our expectation that sales of MuGard will begin in China in the third quarter of 2013, our expectation that we will incur losses for the next several years 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 of activity, performance or achievements expressed or implied by such forward-looking statements.*

### ITEM 1. FINANCIAL 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 and, except as required by law, we do not intend to update any forward-looking statements even if new information becomes available or other events occur in the future.*

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

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

## OVERVIEW

Access Pharmaceuticals, Inc. (together with our subsidiaries, “We,” “Access” or the “Company”) is a Delaware corporation. We are an emerging biopharmaceutical company focused on developing a range of pharmaceutical products primarily based upon our nanopolymer chemistry technologies and other drug delivery technologies. We currently have one marketed product licensed in the U.S. and China. We also have additional products and platform technologies in development where we are seeking partners to continue development and/or to license the technology.

### 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 \$1.0 billion world-wide. MuGard, a proprietary nanopolymer formulation, has received marketing allowance in the U.S. from the FDA. We launched MuGard in the U.S. in the fourth quarter of 2010. On June 6, 2013 we entered into an exclusive license agreement with AMAG Pharmaceuticals, Inc. (“AMAG”) related to the commercialization of MuGard in the U.S. and its territories. Under the terms of the licensing agreement we received an upfront licensing fee of \$3.3 million and a tiered, double-digit royalty on net sales of MuGard in the licensed territories.

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 that commercial sales of MuGard will begin in China in the third quarter of 2013.

We are actively seeking partners to license MuGard in other territories.

For the following products we are seeking partners to continue development and/or are seeking partners to license the technology.

### Product Candidates

- Our candidate for the treatment of cancer is ProLindac™, a nanopolymer Diamino Cyclohexane (“DACH”)-platinum prodrug. ProLindac is in Phase 2 of clinical development and we have completed and evaluated data from several clinical trials with ProLindac. No additional trials are planned and none have been initiated this year in the U.S. or in Europe. We are working with our partners in China towards the initiation of clinical trials of ProLindac in China. 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 (e.g. Eloxatin; Sanofi-Aventis), which has had annual sales in excess of \$2.0 billion. ProLindac is available for partnering.
- CobOral® is our proprietary preclinical nanopolymer oral drug delivery technology based on the natural vitamin B12 oral uptake mechanism. We have developed products based upon the CobOral delivery technology, and have conducted sponsored development of a product for oral delivery of a number of peptides and RNAi therapeutics. The CobOral platform technology is available for partnering.

- CodaCyte®-mediated targeted delivery is a preclinical technology that 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. The CodaCyte platform technology is available for partnering.

## Products and Product Candidates

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

### Access Drug Portfolio

<u>Compound</u>	<u>Originator</u>	<u>Technology</u>	<u>Indication</u>	<u>Clinical Stage (1)</u>
MuGard™	Access	Mucoadhesive liquid	Mucositis	Launched U.S. Licensed to AMAG Pharmaceuticals Regulatory Approval China Licensed to RHEI Pharmaceuticals
ProLindac™ (Polymer Platinate, AP5346)	Access	Synthetic polymer	Cancer	Phase 2
CobOral® Delivery System	Access	Cobalamin	Various	Pre-clinical
CodaCyte®-Targeted Therapeutics	Access	Cobalamin	Anti-tumor	Pre-clinical

(1) For more information, see “Government Regulation” in our Annual Report on Form 10-K for a description of clinical stages.

## RECENT EVENTS

On June 27, 2013 we announced that Dr. Ron R. Allison of Carolina Radiation Medicine, Greenville, NC, presented top-line results from a Phase IV clinical trial evaluating MuGard at the MASCC/ISOO International Symposium on Supportive Care in Cancer in Berlin, Germany. The prospective, randomized, multi-center, double-blind, placebo-controlled study evaluated the efficacy of MuGard in controlling symptoms caused by oral mucositis in 120 patients receiving chemoradiation therapy for the treatment of cancers of the head and neck.

On June 6, 2013 we entered into an exclusive license agreement with AMAG Pharmaceuticals, Inc. (“AMAG”) related to the commercialization of MuGard in the U.S. and its territories. Under the terms of the licensing agreement, we received an upfront licensing fee of \$3.3 million and will receive a tiered, double-digit royalty on net sales of MuGard in the licensed territories. AMAG also purchased our existing MuGard inventory. The \$3.3 million license fee is accounted for as deferred revenue and is recognized over ten years which is the life of the license agreement.

## 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, licensing payments and royalty revenues provided limited funding for operations during the six months ended June 30, 2013. As of June 30, 2013, our cash and cash equivalents were \$1,798,000 and our net cash burn rate for the six months ended June 30, 2013, was approximately \$349,000 per month. As of June 30, 2013, our working capital deficit was \$5,422,000. Our working capital deficit at June 30, 2013 represented an increase of \$474,000 as compared to our working capital deficit as of December 31, 2012 of \$4,948,000. The increase in the working capital deficit at June 30, 2013 reflects six months of net operating costs and changes in current assets and liabilities.

As of August 14, 2013, we did not have enough capital to achieve our long-term goals. If we raise additional funds by selling equity securities, the relative equity ownership of our existing investors will be diluted and the new investors could obtain terms more favorable than previous investors. A failure to obtain necessary additional capital in the future could jeopardize our operations and our ability to continue as a going concern.

We have incurred negative cash flows from operations since inception, and have expended, and expect to continue to expend in the future, substantial funds to complete our planned product development efforts. Since inception, our expenses have significantly exceeded revenues, resulting in an accumulated deficit as of June 30, 2013 of \$263,751,000. 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 first quarter of 2014. However, our ability to fund operations over this time could change significantly depending upon changes to future operational funding obligations or capital expenditures. As a result, we may be required to seek additional financing sources within the next twelve months. We cannot provide assurance that we will ever be able to generate sufficient product revenue or royalty revenue to achieve profitability on a sustained basis or at all.

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 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 2013 COMPARED TO SECOND QUARTER 2012**

Product sales of MuGard in the United States totaled \$380,000 for the second quarter of 2013 as compared with \$615,000 for the same period of 2012, a decrease of \$235,000. The second quarter of 2013 had two months of product sales (as a result of the license of the product in June 2013) while the same period in 2012 had three months of sales. On June 6, 2013, MuGard was licensed to AMAG and future revenue will be recorded as royalties. See sales table in “Critical Accounting Policies and Estimates Relating to MuGard” below.

Our licensing revenue for the second quarter of 2013 was \$84,000 as compared to \$60,000 for the same period of 2012, an increase of \$24,000. We recognize licensing revenue over the period of the performance obligation under our licensing agreements.

We recorded royalty revenue for MuGard in the U.S. for June 2013 of \$3,000. Prior to the license of MuGard to AMAG on June 6, 2013 we recorded product sales for MuGard. We recorded royalty revenue for MuGard in Europe of \$15,000 for the second quarter of 2012 and none in the same period of 2013. In the first quarter of 2012, we finalized the negotiations for the termination of the license to our European partner for MuGard.

Total research and development spending for the second quarter of 2013 was \$197,000, as compared to \$654,000 for the same period of 2012, a decrease of \$457,000. The decrease in expenses was primarily due to:

- decreased salary and related costs (\$186,000) from reduced scientific staff;
- decreased clinical development with trials completed for MuGard, ProLindac , Thiarabine (\$159,000);
- decreased laboratory costs due to the closing of our laboratory (\$64,000); and
- other net decreases in research spending (\$48,000).

Product costs for MuGard in the United States were \$53,000 for the second quarter of 2013 as compared to \$63,000 for the same period in 2012, a decrease of \$10,000.

Total selling, general and administrative expenses were \$2,137,000 for the second quarter of 2013, as compared to \$1,406,000 for the same period of 2012, an increase of \$731,000. The increase in expenses was due primarily to the following:

- increased legal fees (\$335,000);
- increased stock compensation expense from expense of option grants for selling, general and administrative employees (\$166,000);
- increased general business consulting expenses for MuGard licensing transition costs (\$130,000);
- increased MuGard product selling expenses (\$52,000); and
- increased net other general and administrative expenses (\$48,000).

Depreciation and amortization was \$1,000 for the second quarter of 2013 as compared to \$19,000 for the same period in 2012, a decrease of \$18,000, due to assets being fully depreciated.

Total operating expenses for the second quarter of 2013 year were \$2,388,000 as compared to total operating expenses of \$2,142,000 for the same period of 2012, an increase of \$246,000 for the reasons listed above.

Interest and miscellaneous income was \$75,000 for the second quarter of 2013 as compared to no income for the same period of 2012, an increase of \$75,000. Miscellaneous income was higher in 2013 due to write-offs of certain accounts payables.

Interest and other expense was \$43,000 for the second quarter of 2013 as compared to \$169,000 in the same period of 2012, a decrease of \$126,000. The decrease in interest and other expense was due to a pay down in the secured promissory note of \$2.75 million in 2012.

We recorded a gain related to warrants classified as derivative liabilities of \$219,000 for the second quarter of 2013 as compared to \$431,000 for the same period of 2012. We recorded a derivative for warrants when the fair value of the warrants that were issued with our Series A Convertible Preferred Stock were reclassified from equity per the requirements of accounting guidance as a result of the repricing feature.

We recorded a gain for the derivative liability related to preferred stock of \$3,270,000 for the second quarter of 2013 and a loss of \$9,410,000 for the same period of 2012. We recorded a derivative per the requirements of accounting guidance due to the possibility of resetting the conversion price of our Series A Convertible Preferred Stock if we sold our common stock at a price below the conversion price.

Preferred stock dividends of \$733,000 were accrued for the second quarter of 2013 and \$439,000 for the same period of 2012, an increase of \$294,000 due to the issuance of the Series B Preferred Stock. Dividends are due semi-annually in either cash or common stock for the Series A Preferred Stock and due quarterly in either cash or preferred stock for the Series B Preferred Stock.

Net income allocable to common stockholders for the second quarter of 2013 was \$867,000, or a \$0.03 basic income per common share and a \$0.03 diluted income per common share, compared with a net loss of \$11,039,000, or a \$0.46 basic and diluted loss per common share, for the same period in 2012, an increased income of \$11,906,000.

#### **SIX MONTHS ENDED JUNE 30, 2013 COMPARED TO SIX MONTHS ENDED JUNE 30, 2012**

Product sales of MuGard in the United States totaled \$1,542,000 for the first six months of 2013 as compared with \$1,169,000 for the same period of 2012, an increase of \$373,000. Increased product sales were the result of sales growing over 19% per each full quarter during 2012 and the first quarter of 2013. On June 6, 2013, MuGard was licensed to AMAG and future revenue will be recorded as royalties. See sales table in “Critical Accounting Policies and Estimates Relating to MuGard” below.

Our licensing revenue for the first six months of 2013 was \$146,000 as compared to \$1,322,000 for the same period of 2012, a decrease of \$1,176,000. 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.

We recorded royalty revenue for MuGard in the U.S. for June 2013 of \$3,000. Prior to the license of MuGard to AMAG on June 6, 2013 we recorded product sales for MuGard. We recorded royalty revenue for MuGard in Europe of \$36,000 for the first six months of 2012 and none in the same period of 2013. In the first quarter of 2012, we finalized the negotiations for the termination of the license to our European partner for MuGard.

Total research and development spending for the first six months of 2013 was \$520,000, as compared to \$1,404,000 for the same period of 2012, a decrease of \$884,000. The decrease in research and development expenses was primarily due to:

- decreased salary and related costs (\$451,000) from reduced scientific staff;
- decreased clinical development with trials for MuGard, ProLindac and Thiarabine (\$225,000);
- decreased laboratory costs due to the closing of our laboratory (\$121,000);



- decreased stock compensation expense from lower expense of option grants for research and development employees (\$56,000); and
- other net decreases in research spending (\$31,000).

Product costs for MuGard in the United States were \$118,000 for the first six months of 2013 as compared to \$122,000 for the same period in 2012, a decrease of \$4,000 due to increased sales.

Total selling, general and administrative expenses were \$3,475,000 for the first six months of 2013, as compared to \$3,069,000 for the same period of 2012, an increase of \$406,000. The increase in expenses was due primarily to the following:

- increased legal fees (\$307,000);
- increased stock compensation expense from expense of option grants for selling, general and administrative employees (\$162,000);
- increased general business consulting expenses for MuGard licensing transition costs (\$130,000);
- increased MuGard product selling expenses (\$147,000);
- decreased salary and related costs (\$209,000) from reduced general and administrative staff;
- lower patent fees (\$73,000) due to no new patents being filed in 2013; and
- decreased net other general and administrative expenses (\$58,000).

Depreciation and amortization was \$2,000 for the first six months of 2013 as compared to \$73,000 for the same period in 2012, a decrease of \$71,000, due to assets being fully depreciated.

Total operating expenses for the first six months of 2013 were \$4,115,000 as compared to total operating expenses of \$4,668,000 for the same period of 2012, a decrease of \$553,000 for the reasons listed above.

Interest and miscellaneous income was \$169,000 for the first six months of 2013 as compared to \$1,000 for the same period of 2012, an increase of \$168,000. Miscellaneous income was higher in 2013 due to sale of certain platinum inventory and to write-offs of certain accounts payables.

Interest and other expense was \$86,000 for the first six months of 2013 as compared to \$338,000 in the same period of 2012, a decrease of \$252,000. The decrease in interest and other expense was due to the pay-off of the secured promissory note of \$2.75 million in November 2012. For the second quarter of 2013 \$43,000 represents interest accrued on unpaid dividends.

We recorded a one-time expense of \$2,316,000 in the first six months 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 loss related to warrants classified as derivative liabilities of \$28,000 for the first six months of 2013 as compared to a gain of \$1,172,000 for the same period of 2012. We recorded a derivative for warrants when the fair value of the warrants that were issued with our Series A Preferred Stock were reclassified from equity per the requirements of accounting guidance as a result of the repricing feature.

We recorded a gain for the derivative liability related to preferred stock of \$8,050,000 for the first six months of 2013 and a loss of \$11,870,000 for the same period of 2012. We recorded a derivative per the requirements of accounting guidance due to the possibility of resetting the conversion price of our Series A Preferred Stock if we sold our common stock at a price below the original price.

Preferred stock dividends of \$1,460,000 were accrued for the first six months of 2013 and \$879,000 for the same period of 2012, an increase of \$581,000 due to the issuance of the Series B Preferred Stock. Dividends are due semi-annually in either cash or common stock for the Series A Preferred Stock and due quarterly in either cash or preferred stock for the Series B Preferred Stock.

Net income allocable to common stockholders for the first six months of 2013 was \$4,221,000, or a \$0.17 basic income per common share and a \$0.17 diluted income per common share as compared to a net loss of \$16,371,000, or a \$0.68 basic and diluted loss per common share, for the same period in 2012, an increased income of \$20,592,000.

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

We sold MuGard in the U.S. to wholesalers, and specialty and retail pharmacies from September 2010 until June 6, 2013. On June 6, 2013 we licensed MuGard in the U.S. to AMAG Pharmaceuticals. Per the license agreement we will receive royalties from AMAG Pharmaceuticals after that date for its sales of MuGard. We accrued \$3,000 of royalties for June 2013. The \$3.3 million license fee is accounted for as deferred revenue and is recognized over ten years which is the life of the license agreement. We recognized revenue for MuGard product sales at the time title transferred to our customers, which occurred at the time product was shipped to our customers.

We recognized 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 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, 2013	Three months ended June 30, 2013 (1)	Six months ended June 30, 2013
Gross sales	\$ 1,255	\$ 508	\$ 1,763
Cash discounts	10	36	46
Contract discounts	83	92	175
	<u>\$ 1,162</u>	<u>\$ 380</u>	<u>\$ 1,542</u>

  

(in thousands)	Three months ended March 31, 2012	Three months ended June 30, 2012	Six months ended June 30, 2012
Gross sales	\$ 577	\$ 712	\$ 1,289
Cash discounts	5	13	18
Contract discounts	18	84	102
	<u>\$ 554</u>	<u>\$ 615</u>	<u>\$ 1,169</u>

(1) Sales are thru June 6, 2013, the date of the license of MuGard to AMAG Pharmaceuticals.

### 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 management, including the Chief Executive Officer (our principal executive officer) and Chief Financial Officer (our principal financial officer), we have evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e), as of the end of the period covered by this report.

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

Our management, including our principal executive officer and principal accounting officer, conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control—Integrated Framework.

Based on our evaluation, our management concluded in our Annual Report on Form 10-K for the year ended December 31, 2012 that there is a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of control deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

The material weakness identified in our Annual Report on Form 10-K for the year ended December 31, 2012 relates to the monitoring and review of work performed by our Chief Financial Officer in the preparation of audit and financial statements, footnotes and financial data provided to the Company's registered public accounting firm in connection with the annual audit. All of our financial reporting is carried out by our Chief Financial Officer. This lack of accounting staff results in a lack of segregation of duties.

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 based on the criteria established in Internal Control—Integrated Framework issued by COSO. 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 reports are reviewed for reasonableness by the Chief Executive Officer as well as the Chairman of the Audit Committee. All unexpected results are investigated. At any time, if it appears that any control can be implemented to continue to mitigate such weaknesses, it is immediately implemented. As soon as our finances allow, we will hire sufficient accounting staff and implement appropriate procedures for monitoring and review of work performed by our Chief Financial Officer.

#### Changes In Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended June 30, 2013 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.**

Alan Schmidt, a former shareholder of Genaera Corporation ("Genaera"), and a former unitholder of the Genaera Liquidating Trust (the "Trust"), filed a purported class action in the United States District Court for the Eastern District of Pennsylvania in June 2012. The lawsuit named thirty defendants, including the Company, MacroChem Corporation, which was acquired by the Company in February 2009, Jeffrey Davis, the CEO and a director of the Company, and Steven H. Rouhandeh and Mark Alvino, both of whom are Company executives (the "Access Defendants"). With respect to the Access Defendants, the complaint alleges direct and derivative claims asserting that directors of Genaera and the Trustee of the Trust breached their fiduciary duties to Genaera, Genaera's shareholders and the Trust's unitholders in connection with the licensing and disposition of certain assets, aided and abetted by numerous defendants including the Access Defendants. Schmidt seeks money damages, disgorgement of any distributions received from the Trust, rescission of sales made by the Trust, attorneys' and expert fees, and costs. On December 19, 2012, Schmidt filed an amended complaint which asserts substantially the same allegations with respect to the Access Defendants. On February 4, 2013, the Access Defendants moved to dismiss all claims asserted against them. On August 12, 2013 the court granted defendants' motions to dismiss and entered judgment in favor of defendants on all claims.

We are not currently subject to any other material pending legal proceedings.

**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 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. Pursuant to the terms of the Certificate of Designations, Rights and Preferences of our Series B Preferred Stock, we are required to pay dividends in cash or shares of our common stock, semi-annually, at the rate of 12% per annum. The Company has accrued as of June 30, 2013, dividends payable in the aggregate amount of \$5,032,000.

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. A registration statement filed by us relating to a portion of such securities was declared effective on November 13, 2008. However, as of June 30, 2013, 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, 2013, \$857,000 in liquidated damages.

**ITEM 6. EXHIBITS.**

Exhibits:

- |       |  |
|-------|--|
| 3.13  | Certificate of Amendment of Certificate of Incorporation, dated July 1, 2013.  |
| 10.33 | License Agreement, dated June 6, 2013, by and between the Company and AMAG Pharmaceuticals, Inc.   |
| 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, 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.

\*\* These exhibits are interactive data files and are deemed furnished, 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, 2013

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

Date: August 14, 2013

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

	<u>June 30, 2013</u>	<u>December 31, 2012</u>
ASSETS	(unaudited)	
Current assets		
Cash and cash equivalents	\$ 1,798,000	\$ 396,000
Receivables	259,000	840,000
Inventory	-	194,000
Prepaid expenses and other current assets	292,000	251,000
Total current assets	2,349,000	1,681,000
Property and equipment, net	6,000	7,000
Other assets	42,000	42,000
Total assets	\$ 2,397,000	\$ 1,730,000
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities		
Accounts payable	\$ 1,305,000	\$ 2,039,000
Accrued expenses	857,000	857,000
Dividends payable	5,032,000	3,486,000
Current portion of deferred revenue	577,000	247,000
Total current liabilities	7,771,000	6,629,000
Derivative liability - warrants	299,000	271,000
Derivative liability - preferred stock	1,150,000	9,200,000
Long-term deferred revenue	5,530,000	2,706,000
Total liabilities	14,750,000	18,806,000
Commitments and contingencies		
Stockholders' deficit		
Convertible preferred stock Series A - \$.01 par value; authorized 2,000,000 shares; 2,903.3617 shares issued at June 30, 2013 and 2,913.3617 shares issued at December 31, 2012		
Convertible preferred stock Series B - \$.01 par value; authorized 2,000,000 shares; 1,000 shares issued at June 30, 2013 and 1,000 shares issued at December 31, 2012	-	-
Common stock - \$.01 par value; authorized 200,000,000 shares; issued, 25,331,943 at June 30, 2013 and 24,732,312 at December 31, 2012	253,000	247,000
Additional paid-in capital	251,149,000	250,653,000
Treasury stock, at cost – 163 shares	(4,000)	(4,000)
Accumulated deficit	(263,751,000)	(267,972,000)
Total stockholders' deficit	(12,353,000)	(17,076,000)
Total liabilities and stockholders' deficit	\$ 2,397,000	\$ 1,730,000

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



**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Operations  
(unaudited)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2013	2012	2013	2012
Revenues				
Product sales	\$ 380,000	\$ 615,000	\$ 1,542,000	\$ 1,169,000
License revenues	84,000	60,000	146,000	1,322,000
Royalties	3,000	15,000	3,000	36,000
Total revenues	467,000	690,000	1,691,000	2,527,000
Expenses				
Research and development	197,000	654,000	520,000	1,404,000
Product costs	53,000	63,000	118,000	122,000
Selling, general and administrative	2,137,000	1,406,000	3,475,000	3,069,000
Depreciation and amortization	1,000	19,000	2,000	73,000
Total expenses	2,388,000	2,142,000	4,115,000	4,668,000
Loss from operations	(1,921,000)	(1,452,000)	(2,424,000)	(2,141,000)
Interest and miscellaneous income	75,000	-	169,000	1,000
Interest and other expense	(43,000)	(169,000)	(86,000)	(338,000)
Warrant extension expense	-	-	-	(2,316,000)
Gain (loss) on change in fair value of derivative - warrants	219,000	431,000	(28,000)	1,172,000
Gain (loss) on change in fair value of derivative - preferred stock	3,270,000	(9,410,000)	8,050,000	(11,870,000)
	3,521,000	(9,148,000)	8,105,000	(13,351,000)
Net income (loss)	1,600,000	(10,600,000)	5,681,000	(15,492,000)
Less preferred stock dividends	733,000	439,000	1,460,000	879,000
Net income (loss) allocable to common stockholders	\$ 867,000	\$(11,039,000)	\$ 4,221,000	\$(16,371,000)
Net income (loss) per common share				
Basic	\$ 0.03	\$ (0.46)	\$ 0.17	\$ (0.68)
Diluted	\$ 0.03	\$ (0.46)	\$ 0.17	\$ (0.68)
Weighted average number of common shares outstanding				
Basic	25,111,713	24,160,686	24,957,183	24,116,316
Diluted	25,469,229	24,160,686	25,314,699	24,116,316

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Stockholders' Deficit  
(unaudited)

	<u>Common Stock</u>		<u>Preferred Stock – A</u>		<u>Preferred Stock – B</u>		<u>Additional paid-in capital</u>	<u>Treasury stock</u>	<u>Accumulated deficit</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balance December 31, 2012	24,732,312	\$247,000	2,913.3617	\$ -	1,000.0	\$ -	\$250,653,000	\$ (4,000)	\$(267,972,000)
Common stock issued for services	28,043	-	-	-	-	-	10,000	-	-
Common stock issued to employees	73,500	1,000	-	-	-	-	28,000	-	-
Stock option compensation expense	-	-	-	-	-	-	77,000	-	-
Preferred dividends	-	-	-	-	-	-	-	-	(727,000)
Net income	-	-	-	-	-	-	-	-	4,081,000
Balance March 31, 2013	<u>24,833,855</u>	<u>\$248,000</u>	<u>2,913.3617</u>	<u>\$ -</u>	<u>1,000.0</u>	<u>\$ -</u>	<u>\$250,768,000</u>	<u>\$ (4,000)</u>	<u>\$(264,618,000)</u>
Common stock issued for services	174,588	2,000					85,000		
Common stock issued to employees	73,500	1,000					36,000		
Common stock issued for cash exercise of options	50,000	-					11,000		
Preferred stock converted into common stock	200,000	2,000	(10.0000)				(2,000)		
Stock option compensation expense							251,000		
Preferred dividends									(733,000)
Net income									1,600,000
Balance June 30, 2013	<u>25,331,943</u>	<u>\$253,000</u>	<u>2,903.3617</u>	<u>\$ -</u>	<u>1,000.0</u>		<u>\$251,149,000</u>	<u>\$ (4,000)</u>	<u>\$(263,751,000)</u>

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

**Access Pharmaceuticals, Inc. and Subsidiaries**

Condensed Consolidated Statements of Cash Flows  
(unaudited)

	<u>Six Months ended June 30.</u>	
	<u>2013</u>	<u>2012</u>
Cash flows from operating activities:		
Net income (loss)	\$ 5,681,000	\$(15,492,000)
Adjustments to reconcile net income (loss) to cash provided by (used in) operating activities:		
Gain (loss) on change in fair value of derivative - warrants	28,000	(1,172,000)
Gain (loss) on change in fair value of derivative – preferred stock	(8,050,000)	11,870,000
Warrant extension expense	-	2,316,000
Depreciation and amortization	1,000	73,000
Stock option compensation expense	328,000	222,000
Stock issued to directors and employees	66,000	302,000
Stock issued for services	97,000	43,000
Change in operating assets and liabilities:		
Receivables	581,000	(455,000)
Inventory	194,000	(130,000)
Prepaid expenses and other current assets	(41,000)	(5,000)
Other assets	-	8,000
Accounts payable and accrued expenses	(734,000)	697,000
Interest payable on dividends	86,000	172,000
Accrued interest payable	-	166,000
Deferred revenue	3,154,000	(472,000)
Net cash provided by (used in) operating activities	<u>1,391,000</u>	<u>(1,857,000)</u>
Cash flows from investing activities:		
Capital expenditures	-	(15,000)
Net cash used in investing activities	<u>-</u>	<u>(15,000)</u>
Cash flows from financing activities:		
Proceeds from exercise of stock options	11,000	-
Net cash provided by financing activities	<u>11,000</u>	<u>-</u>
Net increase (decrease) in cash and cash equivalents	1,402,000	(1,872,000)
Cash and cash equivalents at beginning of period	396,000	2,460,000
Cash and cash equivalents at end of period	<u>\$ 1,798,000</u>	<u>\$ 588,000</u>
<i>Supplemental cash flow information:</i>		
Cash paid for interest	\$ -	\$ -
<i>Supplemental disclosure of noncash transactions:</i>		
Shares issued for dividends on preferred stock	-	22,000
Preferred stock dividends in dividends payable	\$ 1,460,000	\$ 879,000

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

## Access Pharmaceuticals, Inc. and Subsidiaries

### Notes to Condensed Consolidated Financial Statements Three Months Ended March 31, 2013 and 2012 (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, 2013, the condensed consolidated statements of operations for the three and six months ended June 30, 2013 and 2012, the condensed consolidated statements of stockholders’ deficit for the three and six months ended June 30, 2013, and the condensed consolidated statements of cash flows for the six months ended June 30, 2013 and 2012, 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, 2012. The results of operations for the period ended June 30, 2013 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, 2012 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, 2012 contained an explanatory paragraph to reflect substantial 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 first quarter of 2014. 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, 2013 presentation.

## **(2) Liquidity**

The Company generated net income allocable to common stockholders of \$4,221,000 for the six months ended June 30, 2013 and a loss of \$12,531,000 for the year ended December 31, 2012. At June 30, 2013, our working capital deficit was \$5,422,000. Management believes that our current cash, revenues from MuGard sales and expected license fees should fund our expected burn rate into the first quarter of 2014. We will require additional funds to continue operations. These funds are expected to come from royalties, the future sales of equity and/or license agreements. If we are unable to obtain adequate royalties or 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.

## **(3) 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.

GAAP defines 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. GAAP 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.

GAAP 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, 2013 and December 31, 2012 are summarized below:

(in thousands)

Description	As of June 30, 2013	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability- warrants	\$ 299	\$ -	\$ 299	\$ -	(28)
preferred stock	\$ 1,150	\$ -	\$ -	\$ 1,150	8,050

(in thousands)

Description	As of December 31, 2012	Level 1	Level 2	Level 3	Total Gains (Losses)
Liabilities:					
Derivative liability- warrants	\$ 271	\$ -	\$ 271	\$ -	1,236
preferred stock	\$ 9,200	\$ -	\$ -	\$ 9,200	(4,770)

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, 2013 and December 31, 2012, 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.

#### (4) Stock Based Compensation

For the three and six months ended June 30, 2013, we recognized stock-based compensation expense of \$251,000 and \$328,000, respectively. For the three and six months ended June 30, 2012 we recognized stock-based compensation expense of \$108,000 and \$222,000, respectively.

The following table summarizes stock-based compensation for the three and six months ended June 30, 2013 and 2012:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Research and development	\$ 10,000	\$ 33,000	\$ 19,000	\$ 74,000
Selling, general and administrative	241,000	75,000	309,000	148,000
Stock-based compensation expense included in operating expense	\$ 251,000	\$ 108,000	\$ 328,000	\$ 222,000

For both the three and six months ended June 30, 2013 we granted no stock options. For the three and six months ended June 30, 2012 we granted 510,000 and 510,000 stock options, respectively.

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

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	<u>6/30/12</u>	
Expected life(b)	5.5 yrs	
Risk free interest rate	0.6	%
Expected volatility(a)	96	%
Expected dividend yield	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.

For the three and six months ended June 30, 2012, stock valued at \$232,000 and \$232,000, respectively, was granted to directors and officers.

## **(5) Litigation**

Alan Schmidt, a former shareholder of Genaera Corporation (“Genaera”), and a former unitholder of the Genaera Liquidating Trust (the “Trust”), filed a purported class action in the United States District Court for the Eastern District of Pennsylvania in June, 2012. The lawsuit named thirty defendants, including the Company, MacroChem Corporation, which was acquired by the Company in February 2009, Jeffrey Davis, the CEO and a director of the Company, and Steven H. Rouhandeh and Mark Alvino, both of whom are Company executives (the “Access Defendants”). With respect to the Access Defendants, the complaint alleges direct and derivative claims asserting that directors of Genaera and the Trustee of the Trust breached their fiduciary duties to Genaera, Genaera’s shareholders and the Trust’s unitholders in connection with the licensing and disposition of certain assets, aided and abetted by numerous defendants including the Access Defendants. Schmidt seeks money damages, disgorgement of any distributions received from the Trust, rescission of sales made by the Trust, attorneys’ and expert fees, and costs. On December 19, 2012 Schmidt filed an amended complaint which asserts substantially the same allegations with respect to the Access Defendants. On February 4, 2013, the Access Defendants moved to dismiss all claims asserted against them. On August 12, 2013 the court granted defendants' motions to dismiss and entered judgment in favor of defendants on all claims.

We are not currently subject to any other material pending legal proceedings.

## **(6) Basic and Diluted Net Income (Loss) Per Common Share**

Basic net income or loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income or loss per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options and warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method). In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the “assumed” buyback of additional shares, thereby reducing the dilutive impact of stock options and warrants. Common equivalent shares have not been included in the net loss per share calculations for three and six months ended June 30, 2012, because the effect of including them would have been anti-dilutive.

Basic and diluted net income (loss) per share were determined as follows:

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Net income (loss)	\$ 867	\$ (11,039)	\$ 4,221	\$ (16,371)
Weighted average shares outstanding	25,111,713	24,160,686	24,957,183	24,116,316
Basic net income (loss) per common share	\$ 0.03	\$ (0.46)	\$ 0.17	\$ (0.68)
Net income (loss)	\$ 867	\$ (11,039)	\$ 4,221	\$ (16,371)
Weighted average shares outstanding	25,111,713	24,160,686	24,957,183	24,116,316
Effect of dilutive options and warrants	357,516	-	357,516	-
Weighted average shares outstanding assuming dilution	25,469,229	24,160,686	25,314,699	24,116,316
Diluted net income (loss) per common share	\$ 0.03	\$ (0.46)	\$ 0.17	\$ (0.68)

We did not include the following securities in the table below in the computation of diluted net income (loss) per common share because the securities were anti-dilutive during the periods presented:

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Warrants	35,683,943	15,783,943	35,683,943	15,783,943
Stock options	1,967,284	2,816,284	1,967,284	2,816,284
Preferred stock Series A	58,267,234	20,264,551	58,267,234	20,264,551
Preferred stock Series B	20,000,000	-	20,000,000	-
Total	115,918,461	38,864,778	115,918,461	38,864,778





**CERTIFICATE OF AMENDMENT OF  
CERTIFICATE OF INCORPORATION  
OF  
ACCESS PHARMACEUTICALS, INC.**

Access Pharmaceuticals, Inc. (the "Corporation"), a Delaware corporation, DOES HEREBY CERTIFY:

FIRST: That at a meeting of the directors of the Corporation, a resolution was duly adopted setting forth a proposed amendment of the Certificate of Incorporation of the Corporation, as previously amended, and declaring such amendment to be advisable and calling a meeting of the stockholders of the Corporation for consideration thereof. The resolution setting forth the proposed amendment is as follows:

RESOLVED: That it is advisable that Article V, Section A of the Corporation's Certificate of Incorporation, as amended, relating to the authorized shares of stock of the Corporation be amended by deleting said Article V, Section A in its entirety and substituting the following therefor:

A. The aggregate number of shares of Common Stock which the Corporation shall have authority to issue is Two Hundred Million (200,000,000) shares with a par value of one cent (\$0.01) per share.

SECOND: That thereafter, pursuant to resolution of the Board of Directors, a meeting of the stockholders of the Corporation was duly called and held, upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware, at which meeting the necessary number of shares as required by the General Corporation Law of the State of Delaware voted in favor of the amendment.

THIRD: That such amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

FOURTH: That the effective date of this amendment shall be July 1, 2013.

IN WITNESS WHEREOF, Access Pharmaceuticals, Inc. has caused this Certificate to be executed by Stephen B. Thompson, its Secretary, this 1st day of July, 2013.

By: /s/ Stephen B. Thompson  
Stephen B. Thompson  
Secretary

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

## LICENSE AGREEMENT

This License Agreement (the “Agreement”), is made and entered into on June 6, 2013 (the “Effective Date”) by and between (i) AMAG Pharmaceuticals, Inc., a Delaware corporation, with its principal place of business located at 100 Hayden Ave., Lexington, MA 02421 (“AMAG”) and (ii) Access Pharmaceuticals, Inc., a Delaware corporation, with its principal place of business located at 2600 Stemmons Freeway, Suite 176, Dallas TX 75207 (“Access”) (AMAG and Access are each a “Party,” and collectively the “Parties”).

Whereas, Access has developed and owns or otherwise controls certain intellectual property rights related to the Device (as defined below);

Whereas, AMAG desires to obtain the rights and licenses set forth herein pertaining to the Device;

Now, therefore, in consideration of the mutual covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS

1.1 Certain Defined Terms. Capitalized terms shall have the meaning set forth on Schedule A attached hereto.

### ARTICLE 2 LICENSE

2.1 License Grant. Subject to the terms and conditions of this Agreement, Access, on behalf of itself and its Affiliates, hereby grants to AMAG and its Affiliates (i) an exclusive (even as to Access and its Affiliates), royalty-bearing license, with the right to grant sublicenses, to the Access Intellectual Property Rights in the Territory to use, import, have imported, offer for sale, sell, manufacture and Commercialize the Device for the treatment of all diseases or conditions of the oropharyngeal cavity, including but not limited to, mucositis (such uses are the “Field”), in the Territory and (ii) solely upon the occurrence of a Specified Event, a non-exclusive license, with the right to grant sublicenses, to make and have made the Devices anywhere in the world solely for sale and use in the Territory. The right of AMAG to grant sublicenses under this Section 2.1 is subject to the requirement that each such sublicense shall be in writing and shall include provisions (i) acknowledging that such sublicense is subject to the applicable license(s) granted hereunder, (ii) requiring each sublicensee to perform all applicable obligations of AMAG hereunder in the applicable portion of the Territory (specifically including the obligation to make reports and keep and maintain records of sales to at least the same extent as required under this Agreement), (iii) allowing Access the same access and audit rights with respect to such records as permitted with respect to AMAG’s records hereunder, and (iv) prohibiting further sublicensing by the sublicensee. AMAG shall at all times remain responsible for the

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performance of any of its sublicensees. AMAG shall provide an un-redacted copy of each sublicense it enters into to Access promptly following execution. This Agreement does not convey to AMAG any rights in any Access Intellectual Property Rights, Access Patent Rights or any other intellectual property rights of Access by implication, estoppel or otherwise except for the rights expressly granted in this Section 2.1. Title to the Access Intellectual Property Rights, Access Patent Rights and any other intellectual property rights of Access shall at all times remain vested in Access.

2.2 Ancillary Rights. Access hereby assigns to AMAG all of its right, title and interest (including the right to control access or content) in and to any and all (i) Device-related internet or social media portals or accounts including the domain names www.mugard.com, www.mugard.net, www.mugard.org and the MuGard Facebook page and (ii) intellectual property rights Controlled by Access and its Affiliates, including copyrights, in any and all sales training, and sales, marketing and promotional materials, samples, reprints, speaker kits and product labeling and packaging related to the Device in the Territory. For avoidance of doubt, as of the Effective Date, Access shall cease all Commercialization, marketing, promotion, sales and other public communication relating to the Device in the Territory, by whatever means or media, except as expressly agreed to in advance by AMAG.

2.3 Covenant Not to Compete. Each Party and its Affiliates hereby covenant and agree that during the Term, they will not, directly or indirectly, research, develop, market, sell or Commercialize, or assist in the development, marketing, sale or Commercialization of, any medical devices that directly compete with the Device for the treatment of any diseases or conditions of the oropharyngeal cavity, including but not limited to, Mucositis (a "Competitive Device") in the Territory; including, providing consultative services, owning, managing, operating, participating in, controlling or being connected as a majority stockholder, partner, or otherwise with any Person that creates, develops, markets, sells or Commercializes a Competitive Device, within the Territory.

2.4 Exclusivity. Access hereby agrees that it shall not and it shall cause its Affiliates to not provide the Device to any Third Party if Access or such Affiliate knows or has reason to believe that the units of Device provided to such Third Party have been sold for use or used in the Territory. In the event that Access learns or is notified that the Device is being imported into the Territory by any Third Party to whom Access or any of its Affiliates have directly or indirectly supplied Device without prior written authorization from AMAG ("Diverted Product"), Access and its Affiliates shall take such actions as are necessary to cease such importation, including by terminating agreements with any Third Party involved in the purchase, sale or distribution of such units of Diverted Product. Access further agrees that it shall not and it shall cause its Affiliates to not manufacture, offer for sale, sell or otherwise commercialize, alone or with or through a Third Party, within the Territory, a product that [\*\*\*], that can be used (whether or not such use is in compliance with applicable permits, licenses, authorizations, and clearances required by any Governmental Authority) within the Field. For avoidance of doubt, the foregoing limitation shall not prevent or limit Access's right to manufacture, offer for sale, sell or otherwise commercialize products that [\*\*\*], for the treatment of diseases or conditions outside of the Field.

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2.5 Diligence. AMAG shall use Commercially Reasonable Efforts to Commercialize the Device throughout the Territory during the Term in accordance with the terms and conditions set forth in this Agreement. Notwithstanding the foregoing, AMAG shall provide Access the opportunity to provide commercially reasonable input and suggestions into matters relating to the Commercialization of the Device in the Territory, and AMAG shall not unreasonably refuse to consider such input and suggestions. AMAG shall provide Access with a commercialization plan detailing AMAG's projected activities to Commercialize the Device in the Territory (each, a "Commercialization Plan") within ten (10) days after the end of the [\*\*\*] with updated Commercialization Plans for each calendar year to be provided thereafter not later than March 1 of each such calendar year.

### ARTICLE 3 LICENSE FEES AND ROYALTIES

#### 3.1 Upfront Payments

(a) Effective Date Payment. In consideration of the rights, licenses, representations and warranties granted or made by Access herein, AMAG shall make aggregate payments to Access in the amount of Three Million Three Hundred Thousand U.S. Dollars (\$3,300,000) within five (5) Business Days after receipt of an invoice from Access, such invoice to be delivered on or after the Effective Date.

3.2 Royalties. As consideration for the rights granted pursuant to Section 2.1, AMAG shall pay to Access royalties on aggregate Net Sales of the Device in the Territory for each [\*\*\*] as set forth below:

[***] Net Sales in the Territory [***]	Royalty Rate
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For illustrative purposes, if [\*\*\*], there are Net Sales of the Device in the amount of [\*\*\*], AMAG will pay tiered royalties to Access, in the aggregate amount of [\*\*\*].

3.3 Royalty Term. Royalties shall be payable on Net Sales of the Device beginning on the Effective Date and ending on the last to occur of (i) the expiration or termination of the

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last Valid Claim of the Access Patent Rights to expire or terminate and (ii) the tenth (10<sup>th</sup>) anniversary of the First Commercial Sale of the Device in the Territory (the "Royalty Term"). After the expiration of the Royalty Term, the license granted pursuant to Section 2.1 herein shall become a fully paid-up, royalty-free and perpetual license in the Territory.

3.4 Royalty Reduction. The royalty rates shall be reduced to [\*\*\*] of the rates set forth in Section 3.2 above on Net Sales of the Device in the Territory for any part of the Royalty Term occurring after the expiration or termination of the last Valid Claim of the Access Patent Rights to expire or terminate.

3.5 Royalty Off-Set. AMAG will be entitled to a royalty off-set equal to [\*\*\*] of any amounts actually paid by AMAG to Third Parties in settlement (including a settlement by license) or final judgment of a Third Party claim that the composition of matter, use, manufacture or importation of the Device infringes the patent rights of such Third Party; provided that the application of such offset shall not reduce the royalties owed by AMAG to Access by more than [\*\*\*] of the amount of any royalty payment due hereunder in any calendar quarter (excluding reductions taken in accordance with Section 5.1(a) and with any excess amount that is not recovered pursuant to this Section 3.5 being [\*\*\*]). AMAG shall notify Access if AMAG's royalty obligation is reduced pursuant to this Section 3.5 and AMAG shall include an explanation of the reduction in the applicable royalty report delivered pursuant to Section 3.6.

3.6 Royalty Reports; Payments. The royalty described in Section 3.2 shall be calculated and paid on a calendar quarter basis during the Term. AMAG shall furnish to Access a written report, within forty five (45) days after the end of each calendar quarter (or portion thereof, if this Agreement terminates during a calendar quarter), showing (a) the Net Sales of all Devices sold by AMAG and its Affiliates and Sublicensees in the Territory during the reporting period; (b) the calculation of royalties thereon; (c) the then aggregate Net Sales for Devices for [\*\*\*]; and (d) the calculation of royalties payable under this Agreement for such calendar quarter (or portion thereof). Royalties shown to have accrued by each royalty report shall be due and payable on the date such royalty report is due. All payments to be made by AMAG hereunder will be made in U.S. dollars by wire transfer to such bank account as Access may designate. AMAG shall keep complete and accurate records in sufficient detail to enable the royalties payable hereunder to be determined for a period of at least three (3) years from the date of each payment of royalties.

3.7 Late Payments. In the event that any payment due under this Agreement is not made when due, the amount due shall accrue interest beginning on the [\*\*\*] following the final date on which such payment was due, calculated at the annual rate equal to the prime interest rate reported in the *Wall Street Journal* for the due date, or, if lower, the maximum rate permitted by law, calculated from the due date until paid in full. Such payment when made shall be accompanied by all interest so accrued. Said interest and the payment and acceptance thereof shall not negate or waive the right of the party to whom payment is due to any other remedy, legal or equitable, to which it may be entitled because of the delinquency of the payment.

3.8 Inspections.

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(a) During the term of the Agreement and for a period of three (3) years thereafter, AMAG, its Affiliates and Sublicensees will keep complete and accurate records in sufficient detail to permit Access to confirm the completeness and accuracy of the information presented in each report delivered pursuant to Section 3.6 and all payments due hereunder. AMAG, its Affiliates and Sublicensees will permit an independent, certified public accountant selected by Access and reasonably acceptable to AMAG, which acceptance will not be unreasonably withheld or delayed (the “Auditor”) to audit or inspect those records of AMAG that relate to Net Sales for one or more annual periods, for the sole purpose of verifying the: (i) accuracy of the reports required under Section 3.6 and royalties payable in respect of Net Sales for the period under review; and (ii) withholding taxes, if any, required by law to be deducted as a payment by AMAG in respect of such Net Sales. Such inspections shall be limited to the three (3) preceding calendar years and no period may be subject to such an inspection more than one time hereunder. Such inspections will be conducted during AMAG’s normal business hours at such place where such records are customarily kept, no more than once in any twelve (12) month period and upon at least thirty (30) days prior written notice by Access to AMAG. The Auditor will execute a reasonable written confidentiality agreement with AMAG and will disclose to Access only the amount and accuracy of payments reported and actually paid or otherwise payable under this Agreement and the specific details concerning any discrepancies. The Auditor will send a copy of the report to AMAG at the same time such report is sent to Access.

(b) In the event that the Auditor concludes that additional royalties were required for the annual period under review, the additional royalty payment will be paid within thirty (30) days of the date the Auditor delivers its report to the Parties so concluding that such payments were underpaid. The payment of additional royalties to Access shall bear interest as described in Section 3.7. The fees charged by the Auditor will be paid by Access unless the audit discloses an underpayment of royalties paid or payable by AMAG for the annual period under review by more than the greater of (i) [\*\*\*] or (ii) [\*\*\*], in which case AMAG shall pay (or reimburse Access for) the reasonable and documented fees and expenses charged by the Auditor.

#### **ARTICLE 4 REGULATORY AND PATENT MATTERS**

##### **4.1 Governmental Clearances.**

(a) Access shall obtain and maintain all Governmental Clearances in the Territory concerning the Device and AMAG shall have the right to use and reference all such Governmental Clearances incident to and as an integral part of the License Grant set forth in Article 2 hereof.

(b) Access shall make determinations of whether additional regulatory submissions are necessary to be made to FDA. Access shall provide AMAG with a copy of any additional regulatory submission, including 510(k) premarket notifications submitted for modifications to the Device or other correspondence with FDA exploring whether a 510(k) notice is required for a given Device modification, for AMAG’s review and comment prior to submission. AMAG shall provide such comments to Access within

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fifteen (15) days following its receipt of such materials from Access. Access shall provide AMAG with a copy of the final submission promptly after it is submitted to FDA.

(c) Access and its Affiliates hereby grant to AMAG a [\*\*\*], right of use and reference for any and all data and information contained in any FDA Approvals or filings with FDA, including non-clinical data, and any other data and information required by AMAG in connection with the Commercialization of the Device in the Territory; provided that AMAG shall not seek to utilize such right of reference unless and until [\*\*\*] and AMAG shall not thereafter seek to alter the scope and terms of the Regulatory Clearance for the Device within the Territory without Access's prior written consent, not to be unreasonably withheld or delayed.

(d) Within five (5) Business Days after the Effective Date, Access and AMAG shall enter into an escrow agreement in substantially the form attached hereto as Schedule H (the "Escrow Agreement"). Subject to the terms and conditions set forth in the Escrow Agreement, Access will [\*\*\*] and deposit with the escrow agent identified in the Escrow Agreement (the "Escrow Agent") [\*\*\*] attached hereto as Schedule E [\*\*\*] to release from escrow [\*\*\*] if a Release Event occurs pursuant to Section 4.9 of this Agreement. [\*\*\*].

#### 4.2 Compliance with Applicable Laws - General.

(a) Each Party shall comply in all material respects with all Applicable Laws that relate to the performance of such Party's obligations under this Agreement and, except as provided for herein, shall bear their own cost and expense of complying therewith.

(b) The termination or expiration of this Agreement shall not relieve either Party of its responsibility to comply in all material respects with any statutory or regulatory requirements associated with the Device(s).

(c) Each Party shall be responsible for compliance, as applicable, with FDA's establishment registration and device listing requirements set forth in 21 C.F.R. Section 807.25.

(d) Access shall be responsible for compliance, as applicable, with FDA's medical device reporting requirements set forth in 21 C.F.R. Part 803.25.

(e) Each Party shall be responsible for compliance, as applicable, with FDA's corrections and removals requirements as set forth in 21 C.F.R. Part 806.

#### 4.3 Good Manufacturing Practices.

(a) Access shall ensure that all Devices are designed and manufactured in material compliance with (i) FDA's Good Manufacturing Practices,



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which are codified in the Quality System Regulation (“QSR”) set forth in 21 C.F.R. Part 820, (ii) the Quality Agreement and (iii) the Supply Agreement.

(b) AMAG shall ensure that it conducts any QSR-related activities in substantial compliance with FDA’s requirements, as necessary. Without limiting the generality of the foregoing, such activities may include, among others, incoming inspections, warehousing and storage, Device handling and maintenance of distribution records. All Device Returns which are to be quarantined and marked in such a fashion as to not be confused with inventory for sale, and warehousing in a manner that prevents damage to Devices.

#### 4.4 Device Complaints.

(a) Access shall be responsible for handling all complaints, inquiries and any medical or non-medical device reporting requirements associated with the Devices. Access or its Affiliates will be responsible for maintaining Device complaint files and for submitting reports to the FDA regarding such complaints. Access is responsible for complying with all Applicable Laws pertaining to the reporting of adverse device events or malfunctions, including FDA’s Medical Device Reporting requirements, as set forth at 21 C.F.R Part 803. AMAG shall cooperate fully with Access to enable Access to fulfill such requirements. Access shall provide AMAG with a copy of any response related to a request for information from FDA’s Office of Surveillance and Biometrics for AMAG’s review and comment prior to submission of the response. Access shall provide AMAG with a copy of the final response promptly after it is submitted to FDA.

(b) If AMAG receives any information regarding real or potential adverse reactions or malfunctions of the Device(s) or any information that might otherwise constitute a complaint about the Device(s), AMAG shall promptly provide to Access all information that it has concerning same. AMAG shall, at Access’s request, assist with the investigation of complaints by requesting reasonably obtainable follow-up information from its customers. Upon the request of AMAG, AMAG and Access shall promptly enter into a separate agreement to further specify the allocation of responsibilities set forth in this Section 4.4(b).

(c) In the event and to the extent that [\*\*\*] manufacture, handling, storage or testing of the Devices facilities, [\*\*\*], Access shall delegate to AMAG its responsibilities for complaint handling and MDR reporting under 21 C.F.R. Part 803, until [\*\*\*]. Access shall cooperate fully with AMAG to enable AMAG to fulfill such requirements and shall promptly provide access to existing complaint files and MDRs. Once AMAG [\*\*\*], all complaint handling and MDR reporting shall [\*\*\*] with respect to Devices manufactured [\*\*\*] but not with respect to Devices manufactured [\*\*\*].

#### 4.5 Quality Inspections By AMAG.

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(a) Routine. Access and its Affiliates shall permit and facilitate AMAG (or an independent quality control auditor reasonably acceptable to Access), once each calendar year, for a period not to exceed three (3) days, during regular business hours and upon at least five (5) Business Days notice, access to inspect Access and the facilities where the Devices were managed or are manufactured, handled, stored or tested.

(b) For Cause. In addition, AMAG or its auditor shall have the right to inspect Access and the facilities where the Devices were managed or are manufactured, handled, stored or tested for a period not to exceed three (3) days, during reasonable business hours and upon at least four (4) Business Days notice where a substantial question concerning the quality of the Devices or manufacturing facilities or process has been raised by FDA or as a result of Device defect or Device-related claims of injury, including a follow up inspection to ensure implementation of any needed corrective action.

(c) During such inspections, AMAG or its auditor may observe all processes relating to the management or manufacture, storage, handling or testing of the Devices and all management, manufacturing, handling, storage and test records regarding the Devices to the extent necessary for, and for the sole purpose of, assessing Access's compliance with the provisions of Sections 4.2, 4.3 and the product warranty set forth in Schedule E to this Agreement. Access shall provide reasonable and customary assistance during such inspections.

(d) AMAG and its auditor shall observe all rules applicable to visitors while on site at Access and its Affiliates. AMAG shall use reasonable efforts to ensure that such inspections do not unreasonably disrupt operations of the applicable facility, and acknowledges that in complying with its inspection obligations Access and its designees shall be entitled to protect the confidentiality of records, facilities and processes not related to the Device or the manufacturing or quality control processes relating to the Device.

(e) AMAG shall only be permitted to use an auditor who first executes a confidentiality agreement reasonably acceptable to Access and its Affiliates or designated third party manufacturers, as applicable.

(f) AMAG shall cause the auditor to provide Access and its Affiliates with a copy of any written materials reporting on the results and conclusions of such inspection contemporaneously with any such submission to AMAG.

(g) If an inspection pursuant to this Section 4.5 reveals that the facility used to manufacture Devices does not satisfy the requirements of Section 4.2 and Section 4.3 in all material respects, then AMAG will promptly provide to Access written notice of such fact, which notice will contain in reasonable detail the deficiencies alleged in the manufacturing facilities and, if practicable, those steps AMAG believes Access should undertake in order to remedy such deficiencies. Access will remedy such deficiencies

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according to a mutually agreed plan to be established within [\*\*\*] days after receipt of such written notice.

(h) In the event and to the extent that [\*\*\*] manufacture, handling, storage or testing of the Devices facilities, whether directly or indirectly, then the provisions of Section 4.5(a)-(g) shall thereafter [\*\*\*].

#### 4.6 Device Recalls.

(a) If either Party (i) becomes aware of an event, incident or circumstance that has occurred which may result in the need for a recall or other removal of the Device or any lot or lots thereof from the market; (ii) becomes aware that a Governmental Authority is threatening or has initiated an action to remove the Device from the market; or (iii) is required by any Governmental Authority to distribute a "Dear Doctor" letter or its equivalent, regarding use of the Device, such Party shall promptly advise the other Party in writing with respect thereto, and shall provide to such other Party copies of all relevant correspondence, notices, and the like. The Parties will promptly confer to discuss such circumstances and to consider appropriate courses of action. The Parties shall mutually agree upon any corrective action with respect to the Device in the Territory; provided that in the event that they are unable to agree then Access shall have final authority to make all decisions relating to any recall, market withdrawal or other corrective action with respect to the Device in the Territory and shall be responsible for conducting any recalls or taking such other remedial action, and AMAG agrees, upon reasonable request by Access and [\*\*\*], to assist with respect to such recalls or remedial actions.

(b) If Access decides to conduct a recall, market withdrawal or other corrective action with respect to the Device in the Territory Access will provide written notice to AMAG within twenty-four (24) hours of such decision, and a summary of the reason for and implementation of such action. Access shall provide such information as AMAG may reasonably require to prepare any additional customer notification of such recall, which notification shall be issued by AMAG.

(c) Any such recall shall be handled in accordance with the policies and procedures maintained by the recalling party. The recalling party shall submit to FDA, any necessary reports, as required under 21 C.F.R. Part 806, and shall be responsible for drafting any recall notifications with respect to the Devices. Access shall provide AMAG with a copy of any report for AMAG's review and comment prior to submission. Access shall provide AMAG with a copy of the final report promptly after it is submitted to FDA.

(d) In the event of a recall, market withdrawal or other corrective action with respect to the Device in the Territory in accordance with Section 4.6, [\*\*\*] shall be responsible for all costs and expenses of such recall, market withdrawal or other corrective action to the extent such recall, market withdrawal or other corrective action is caused by a breach of this Agreement or the Supply Agreement [\*\*\*] or the failure of

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[\*\*\*], its Affiliates or contractors to comply with any FDA requirement and [\*\*\*] shall, at its option, either [\*\*\*] the Devices that are the subject of such action or [\*\*\*] the Devices that are the subject of such action [\*\*\*] within a reasonable time at its expense. [\*\*\*] shall be responsible for the cost and expenses of any recall, market withdrawal or other corrective action with respect to the Device in the Territory to the extent that such recall, market withdrawal or other corrective action is caused by a breach of this Agreement by [\*\*\*] or the failure of [\*\*\*], its Affiliates or contractors to comply with any FDA requirement.

(e) During the term of this Agreement, AMAG shall maintain records of all sales of the Devices, including Devices sold, quantities and shipment dates, and customer information sufficient to adequately administer a recall, market withdrawal or correction and provide Access with such materials in the event and to the extent necessary to implement a recall, market withdrawal or correction. Immediately upon termination or expiration of this Agreement, AMAG shall provide Access with a copy of all distribution records relating to the Devices.

#### 4.7 Governmental Inspections and Inquiries.

(a) Access and its Affiliates shall promptly, and in any event within [\*\*\*] after the date of receipt of notice, notify AMAG in writing of, and shall provide AMAG with copies of, any correspondence and other documentation received or prepared by Access in connection with any of the following events to the extent necessary to meet the requirements of FDA or other Governmental Authority:

- i. receipt of a regulatory letter, warning, recall notice, notice of FDA or other Governmental Authority in connection with the design, manufacture, storage, marketing, advertisement, sale and/or distribution of the Devices; and
- ii. any FDA or other Governmental Authority comments relating to the Devices that may require a response or action by Access or its Affiliates.

(b) Without limiting the generality of the foregoing, in the event that AMAG or any of its agents receives a letter or comments from FDA or other Governmental Authority in connection with any of the Devices that requires a response or action by AMAG, Access shall promptly provide to AMAG any data or information required in preparing such response that relates to storage, marketing, advertising, sale or distribution of the Devices, and Access will cooperate fully with AMAG in preparing such response.

(c) In the event any facility that is used by Access or Affiliates to manufacture, store, market, advertise, distribute or sell any of the Devices is inspected by FDA or other Governmental Authority, Access shall notify AMAG promptly upon learning of such inspection and shall supply AMAG with copies of any correspondence

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that relates to such inspection. AMAG may, at its election, send representatives to such facility and may observe any portion of such inspection that relates to the Device and provide input to Access. Access shall provide AMAG with a copy of any response related to such visit or inspection for AMAG's review and comment prior to submission of the response. Access shall provide AMAG with a copy of the final response promptly after it is submitted to FDA or such other Governmental Authority.

4.8 AMAG Regulatory Requirements. AMAG shall at all times promote, advertise, market, distribute and sell the Device in accordance with all Applicable Laws.

#### 4.9 Specified Events.

(a) In the event that a Specified Event occurs, (i) AMAG shall have the right, but not the obligation, to certify to the Escrow Agent that a Specified Event that is a Release Event has occurred and [\*\*\*] and/or (ii) AMAG shall have the right, but not the obligation, [\*\*\*]. Access shall promptly take such other actions as AMAG may reasonably request to assist AMAG in [\*\*\*], including without limitation by providing the following:

[\*\*\*]

(b) Access shall also grant AMAG the rights to [\*\*\*] in cooperation with any Third Party manufacturer, including [\*\*\*], for the manufacture of the Device, and shall issue a corresponding release to such Third Party to release it of any obligations that would interfere with [\*\*\*]. Upon [\*\*\*], the exclusive US license for [\*\*\*] shall continue in effect for the full Term. Upon [\*\*\*] the provisions of [\*\*\*] shall continue in effect with all references in such Sections [\*\*\*] being deemed [\*\*\*] and all references in such Sections [\*\*\*] being deemed [\*\*\*]. For the avoidance of doubt, if AMAG exercises [\*\*\*] rights in accordance with [\*\*\*] then [\*\*\*] shall not bear any obligations under this Agreement or the Supply Agreement in respect of [\*\*\*].

(c) A Specified Event shall be any of the following (each a "Specified Event"):

- Access [\*\*\*] addressed to Access or its Affiliates or its Third Party contract manufacturer within the time period established in a [\*\*\*] (or any extension of such time period [\*\*\*]) (“[\*\*\*]”);
- Access or its Affiliates or its Third Party contract manufacturer [\*\*\*] according to a [\*\*\*] that is the subject of a notice delivered to Access pursuant to [\*\*\*];
- [\*\*\*];

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- [\*\*];
- Access acquiesces to any [\*\*], or if Access contests such action, such case is not dismissed within 60 days of its initial filing (“[\*\*]”); or
- [\*\*] and together with the [\*\*], each a “Release Event” and collectively, the “Release Events”).

#### 4.10 Patent Matters.

(a) *Patent Maintenance*. Access shall be responsible for the preparation, prosecution (excluding, any interferences, reissue proceedings and reexaminations) and maintenance of the Access Patent Rights [\*\*]. Upon request by AMAG, Access shall provide AMAG with an update of the filing, prosecution and maintenance status for each of the Access Patent Rights. Access shall reasonably consult with, and will accommodate requests made by, AMAG with respect to the preparation, prosecution and maintenance of the Access Patent Rights in the Territory. Access shall provide to AMAG copies of any papers relating to the filing, prosecution or maintenance of the Access Patent Rights in the Territory promptly upon their being filed or received. Access shall not knowingly take any action during prosecution and maintenance of the Access Patent Rights that would materially adversely affect them (including abandonment or any reduction in claim scope), without AMAG’s prior consent. [\*\*].

(b) *Patent Enforcement*. In the event that Access or AMAG becomes aware of a suspected infringement in the Territory of any Access Patent Right exclusively licensed to AMAG under this Agreement, or any such Access Patent Right is challenged in any action or proceeding (including any interferences, reissue proceedings or reexaminations), such Party shall notify the other Party promptly, and following such notification, the Parties shall confer. [\*\*] shall have the first right, but shall not be obligated, to bring an infringement action with respect to such infringement at its own expense, in its own name, provided, that [\*\*] keeps [\*\*] reasonably informed of its progress and provides [\*\*] with copies of any substantive documents related to such proceedings and reasonable notice of all such proceedings. [\*\*] shall make reasonable efforts to assist [\*\*], at [\*\*] request and expense, in any action or proceeding being prosecuted if so requested, and shall lend its name to such actions or proceedings if reasonably requested by [\*\*] or required by Applicable Law. If [\*\*] recovers any damages or other sums in any such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith, including, without limitation, attorney’s fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total of such costs and expenses incurred by each Party. If after such reimbursement any funds shall remain from such damages or other sums recovered, such funds shall be retained by [\*\*], provided that

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[\*\*\*] shall receive out of any such remaining recovery received by [\*\*\*] an amount equivalent to [\*\*\*]. [\*\*\*] shall notify [\*\*\*] of its decision to exercise its right to enforce or defend the [\*\*\*] as soon as possible, but not later than [\*\*\*] following its discovery or receipt of notice of the alleged infringement. If (i) [\*\*\*] notifies [\*\*\*] that it will not [\*\*\*] in accordance with this Section 4.4(b); (ii) [\*\*\*] has exhausted all legal appeals with respect to causing the alleged infringement to cease or causing the Person alleging the infringement to forebear or (iii) [\*\*\*] fails to bring an infringement action within [\*\*\*] following its discovery or receipt of notice of the alleged infringement; or (iv) [\*\*\*] is not reasonably diligent in pursuing an infringement action or diligently defending the validity or enforceability of [\*\*\*] at issue and, after notice from [\*\*\*], fails to exercise reasonable diligence in connection with such activities, then [\*\*\*] shall have the right to pursue the alleged infringer or take control of any action initiated by, or being defended by, [\*\*\*] at [\*\*\*] own expense. Notwithstanding the foregoing, if [\*\*\*] has not initiated an infringement or misappropriation action as described under (iii) above, or ceased to pursue such action, on the advice of outside patent counsel, then [\*\*\*] agrees not to initiate such an action without [\*\*\*] prior consent not to be unreasonably withheld or delayed (with the determination of reasonableness taking into account the costs of such litigation, its likelihood for success, the potential damages or settlement recovery). In any such case, [\*\*\*] will, wherever possible under Applicable Law, substitute [\*\*\*] as party plaintiff for purposes of pursuing any alleged infringer, or as defendant for defending any [\*\*\*]. If [\*\*\*] recovers any damages or other sums in any such action, suit or proceeding or in settlement thereof, such damages or other sums recovered shall first be applied to all out-of-pocket costs and expenses incurred by the Parties in connection therewith, including, without limitation, attorneys fees. If such recovery is insufficient to cover all such costs and expenses of both Parties, it shall be shared in proportion to the total of such costs and expenses incurred by each Party. If after such reimbursement any funds shall remain from such damages or other sums recovered, such funds shall be retained by [\*\*\*]. No settlement, consent judgment or other voluntary final disposition of any suit regarding [\*\*\*] in the Territory may be entered into by AMAG or Access without the consent of the other Party, which consent shall not be unreasonably withheld or delayed.

## **ARTICLE 5 TRANSITION PERIOD**

5.1 Transition Period. Access will perform the transition activities described in this Section 5.1 as soon as reasonably possible after the Effective Date. AMAG shall use reasonable efforts to support Access's performance of such activities and shall otherwise cooperate in good faith with Access in connection therewith.

### *(a) Retained Sales; Retained Liabilities .*

(i) For avoidance of doubt, as between the Parties, Access shall retain all rights and liabilities associated with Devices sold by or on behalf of Access either outside of the Territory at any time or within the Territory but prior to the

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Effective Date (“Retained Sales”). Without limiting the foregoing, Access shall have the sole right to collect any and all amounts that are due and payable from Third Parties in connection with Retained Sales. Access shall retain sole responsibility for all costs, expenses, claims and liabilities associated with the manufacture, marketing, distribution, sale or use of the Device prior to the Effective Date (such amounts are collectively, the “Retained Liabilities”), including, liability for fees, services and claims arising under or related to any Third Party Agreements (including and such liability relating to Third Party Agreements that are assigned to AMAG to the extent incurred or accrued prior to such assignment), liability for all returns, rebates, credits, chargebacks, administrative fees, price adjustment claims and liabilities and all liabilities for damage or personal injury, including product liability claims, arising out of or relating to Retained Sales or the research, development and Commercialization of the Device by or on behalf of Access or any of its Affiliates.

(ii) *AMAG Right to Cure and Offset.* Notwithstanding the allocation of responsibility in Section 5.1(a)(i), in order to avoid confusion within the Territory, AMAG shall have the right, to be exercised if at all in AMAG’s sole discretion, to accept returns and to honor rebates, credits, price adjustments and similar claims and liabilities made or requested in connection with Retained Sales and Access hereby agrees (A) that Access shall reimburse AMAG for such costs incurred by AMAG in connection with such activities, including the amounts of such rebates, credits, price adjustments and other similar claims within thirty (30) days after receipt of an invoice therefor from AMAG and (B) that as an alternative to such reimbursement, AMAG shall be permitted to offset such costs against payments that become due hereunder from AMAG to Access.

(iii) *Excess Load In.* To the extent that Access (directly or with or through any Third Parties) shipped, distributed or sold a quantity of Devices within the Territory during the [\*\*\*] period ending on the Effective Date that has an aggregate gross invoiced price in excess of [\*\*\*] (such excess amount is the “Excess Load In Charge”) and will be subject to reimbursement or offset as set forth in this Section 5.1(a)(iii). Access hereby agrees (A) that Access shall reimburse AMAG in an amount equal to [\*\*\*] of the Excess Load In Charge within [\*\*\*] after receipt of an invoice therefor from AMAG and (B) that as an alternative to such reimbursement, AMAG shall be permitted to offset such costs against payments that become due hereunder from AMAG to Access.

(b) *Commercial Agreements.* Beginning on the Effective Date, and for a period of [\*\*\*] thereafter, the Parties shall cooperate in good faith to (1) negotiate and effectuate the assignment of such Third Party Agreements to AMAG as AMAG may request, (2) to terminate such Third Party Agreements as AMAG may direct, and (3) to either maintain in effect for the benefit of AMAG (including that Access will exercise rights thereunder at AMAG’s direction) provided that AMAG performs any obligations thereunder or compensates Access for the cost of its performance, or make reasonable efforts to facilitate AMAG negotiation and entry into agreements with such Third Parties as AMAG may request, including that Access shall agree to terminate or waiver or modify its rights under any Third Party Agreements with such Third Parties with respect



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to the Territory as necessary or convenient to facilitate such entry by AMAG. The Parties further agree that Access shall use reasonable efforts to maintain in effect the arrangement pursuant to which [\*\*\*] provides [\*\*\*] services for the Device in the Territory on behalf of Access in the same manner as such services have been provided for Access with only such modifications as AMAG shall direct, until the earlier of [\*\*\*] or [\*\*\*] after AMAG notifies Access of its desire to terminate such services (the “[\*\*\*] Transition Period”); provided that: (1) such performance shall be for the benefit of AMAG and provided subject to AMAG’s policies and procedures provided to Access in writing, (2) Access receives a written commitment from [\*\*\*] on or before the Effective Date in the form attached hereto as Schedule G; and (3) Access shall promptly provide invoices for such services that are provided by [\*\*\*] to Access and AMAG shall pay such invoices [\*\*\*]. Notwithstanding anything herein to the contrary, to the extent that AMAG determines during the [\*\*\*] Transition Period, that any of the Third Party Agreements identified in Schedule D to be assigned to AMAG or maintained by Access for the benefit of AMAG (as set forth in this Section 5.1(b)), could result in an actual or potential violation of the Healthcare Law, AMAG shall have the right to forego such assignment or maintenance of such Third Party Agreements, and AMAG and Access shall cooperate fully to facilitate the modification of such Third Party Agreement(s), or cancellation/termination and renegotiation of such Third Party Agreement(s). In no event shall AMAG be bound to accept assignment or maintenance (by Access) of any Third Party Agreement where it reasonably believes that such Third Party Agreement could result in an actual or potential violation of the Healthcare Law.

(c) *Inventory*. Access shall transfer to AMAG [\*\*\*] of the Devices (not to exceed an aggregate of [\*\*\*]) held by Access or its Affiliates (the “Inventory”); provided that such Inventory is in good, salable condition, has been manufactured, packaged, shipped and stored in compliance with all applicable regulations, the Regulatory Clearance and specifications and has no less than [\*\*\*] of remaining shelf life. The price for such Inventory shall be [\*\*\*]. AMAG shall pay Access for such Inventory within [\*\*\*] Business Days after receipt of an invoice from Access, such invoice to be delivered on or after the Effective Date.

(d) *Employees and Consultants*. Access will identify employees and consultants retained by Access that have been involved in the research, development and Commercialization of the Device prior to the Effective Date and will facilitate introductions as requested by AMAG and will waive any non-compete or other restrictions or rights that Access has to limit or block AMAG from retaining or employing any such individuals as of and after the Effective Date in connection with its performance hereunder

(e) *Further Assurances*. Access agrees to take such actions, including executing and delivering such documents, as AMAG shall reasonably request on or after the Effective Date, to give effect to the terms set forth in this Agreement, including this Section 5.1. Access agrees to make its employees and advisors reasonably available to answer questions from and otherwise provide assistance and information to AMAG as AMAG may request to facilitate AMAG’s performance of its obligations hereunder.

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(f) *Quality Agreement and Supply Agreement*. Within [\*\*\*] after the Effective Date, the Parties shall enter into a supply agreement (the “Supply Agreement”) governing the supply of Product to AMAG in finished form for commercial use and for use as samples and within [\*\*\*] after the Effective Date, the Parties shall enter quality agreement governing the quality control and quality assurance procedures thereon (the “Quality Agreement” and collectively the “Quality and Supply Agreements”) and any other operational agreements and procedures as deemed necessary by the Parties for such supply of the Product by Access or its designated Third Party contract manufacturer(s) to AMAG. The terms of such Quality and Supply Agreements shall be negotiated in good faith by the Parties in accordance with the terms of Schedule E. The Quality and Supply Agreements shall include, in addition to those terms specified in Schedule E, provisions that provide that if Access is unable to supply the Devices ordered by AMAG in accordance with the terms of the Quality and Supply Agreements, then Access shall use Commercially Reasonable Efforts to remedy the problem or secure an alternative source of supply within a reasonable time at no cost to AMAG, and any such alternative source of supply shall be on terms substantially similar with the terms of the Quality and Supply Agreements. If Access is unable to remedy the problem or secure an alternative source of supply in time to avoid an out of stock situation, then Access shall consult with AMAG and the Parties shall work together to remedy the problem. At that time, AMAG may at its option, and upon notice to Access, have the right to work directly with the existing source of the supply to remedy the problem or manufacture the Devices itself or through a Third Party. If AMAG notifies Access that AMAG will make the Devices itself or through a Third Party, Access shall (i) deliver to AMAG within ten (10) days media embodying or disclosing all technology and proprietary or intellectual property rights necessary to enable AMAG or its designee to manufacture Devices conforming with the Specifications; (ii) provide AMAG or its designee, upon request, with assistance in establishing a manufacturing line, and (iii) file as required any documentation with the FDA to be provided by AMAG to allow for the distribution of Devices produced by the Third Party in the Territory. AMAG shall continue to pay to Access the royalty due under Section 3.2 for all Devices manufactured by AMAG (or any Third Party selected by AMAG) and sold by AMAG pursuant to this Section 5.1(f); provided that if Access desires to make use of a Second Source for supply needs outside the Territory, the Parties shall use good faith efforts to agree [\*\*\*], based on the volumes supplied for each such territory. AMAG shall require any Third Party AMAG designates to manufacture Devices pursuant to this Section 5.1(f) to agree in writing to observe the terms of the Quality and Supply Agreements relating to confidentiality and the manufacture of Devices. Notwithstanding any provision of this Section 5.1(f) to the contrary, in no case shall Access be required to pay AMAG in respect of any Devices purchased by AMAG from a Third Party operating a back-up manufacturing line established pursuant to this Section 5.1(f) or manufactured by AMAG or its Affiliates pursuant to this Section 5.1(f).

(g) *Credits of Certain [\*\*\*] Payments*. [\*\*\*]. In the event that [\*\*\*] then Access shall be entitled to payment by the relevant [\*\*\*] in respect of sales of the Device to the [\*\*\*] covered by the [\*\*\*]. In the event and to the extent that AMAG receives payments from such [\*\*\*] in respect of sales of the Device to such [\*\*\*] during

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the period prior to the Effective Date, then AMAG shall credit and pay such amounts to Access. In the event and to the extent that Access receives chargebacks from third-party wholesalers relating to such [\*\*\*] in respect of sales of the Device on behalf of AMAG to such [\*\*\*] during the period after the Effective, Date then Access shall invoice AMAG and AMAG shall credit and pay such amounts to Access.

## **ARTICLE 6 TERM AND TERMINATION**

6.1 Term. The term of this Agreement shall take effect as of the Effective Date and shall expire at the end of the Royalty Term unless sooner terminated as provided herein (the "Term").

6.2 Termination. Notwithstanding anything in Section [6.1](#), this Agreement may be terminated at any time as follows:

(a) By either Party upon delivery of written notice to the other Party in the event of any breach by such other Party of any of such other Party's material obligations under this Agreement, provided that such breach has not been cured within [\*\*\*] after written notice thereof is given by the non-breaching Party to the breaching Party specifying the nature of the alleged, provided that, if a cure is not feasible within such [\*\*\*] period, the cure period shall be extended (i) if the Parties agree that the breaching Party is using good faith reasonable efforts to cure such breach; or (ii) the existence of a material breach is the subject of an Arbitration Request.

(b) By AMAG at any time and without cause by providing at least one hundred and eighty (180) days prior notice of termination to Access or immediately upon written notice to Access if the FDA or any other Governmental Authority within the Territory enjoins on a permanent basis, the marketing, sale or use of the Device within the Field.

(c) By either Party at any time during the Term by providing written notice with immediate effect in the event that: (i) the other Party files in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for a similar arrangement or for the appointment of a receiver or trustee of that Party or of its assets, other than the commencement of a proceeding under the Bankruptcy Code (11 U.S.C. § 101, et seq) or the appointment of a trustee in such a proceeding, or (ii) if the other Party proposes a written agreement of composition or extension of its debts generally, or (iii) if the other Party proposes or is a party to any voluntary dissolution or liquidation or is served with an involuntary petition for dissolution or liquidation under the Bankruptcy Code (11 U.S.C. § 101, et seq) that is not dismissed within sixty (60) days after the filing thereof, or (iv) if the other Party makes an assignment for the benefit of its creditors.

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(d) At any time upon mutual written agreement of the Parties.

6.3 Effect of Termination. Upon termination of this Agreement pursuant to Section [6.2](#) herein:

(a) all rights and licenses granted to AMAG and its Affiliates under this Agreement will terminate, and AMAG and its Affiliates and Sublicensees will cease all use of Access Intellectual Property Rights; all agreements with Sublicensees shall provide that such sublicense agreements shall terminate upon any termination of this Agreement;

(b) AMAG shall, at Access's written request and [\*\*\*] promptly assign and transfer to Access all of AMAG's right, title and interest in and to all Governmental Clearances, regulatory filings, clinical trial agreements and other data relating to the use, sale, offer for sale or importation of the Device in the Territory, including (1) data, materials, and information relating to non-clinical, pre-clinical and clinical activities and clinical trials; (2) samples of promotional, sales, marketing, and educational materials for the Device that describe the features or benefits of the Device, as such materials then currently exist that are related exclusively to the use, sale, offer for sale or importation of the Device ("Promotional Materials") (each of which shall be transferred in any event within ninety (90) days after AMAG's receipt of such request), in each case solely to the extent directly related to, and actually used by AMAG in connection with, the Device as of the effective date of termination. AMAG shall cooperate with Access in the assignment and transfer pursuant to this Section 6.3(b) to support ongoing Commercialization with minimal disruption and to the extent any materials described in this Section 6.3(b) are not transferable, AMAG shall use Commercially Reasonable Efforts to make such materials available to Access. Upon termination by Access pursuant to Section 6.2(a) or by AMAG pursuant to Section 6.2(b), (A) Access shall continue to have the right to use all aspects of the Promotional Materials (other than AMAG house marks) and to make derivative works based thereon, solely in connection with the Commercialization of the Device in the Territory; and (B) AMAG shall assign to Access those trademarks (if any) owned by AMAG and used solely in connection with the Commercialization of the Device and on the Promotional Materials as of the effective date of termination (excluding AMAG house marks) at Access's cost, solely for the purpose of making, using, selling, offering for sale and importing such Devices in the Territory. AMAG shall own all right, title, and interest in and to any such Promotional Materials, including applicable copyrights and AMAG housemarks, but excluding trademarks assigned to Access as provided above;

(c) AMAG shall have the right to sell its remaining supply of Devices in the Territory [\*\*\*] following any such termination, subject to the payment of royalties due under [Article 3](#) hereof;

(d) Nothing herein shall be construed to release either Party of any obligation that matured prior to the effective date of any termination. Either Party's

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liability for any uncontested charges, payments or expenses due to the other Party that accrued prior to the termination date shall not be extinguished by termination, and such amounts (if not otherwise due on an earlier date) shall be immediately due and payable on the termination date;

(e) Sections 1, 2.1 (with respect only to the conversion of the license granted on expiration of the Royalty Term as described in Section 3.3), 3.3 (with respect only to the conversion of the license granted in Section 2.1), 3.5, 3.8, 5.1(a), 6.3 (and the Sections referenced therein), 7.3, 7.4, 7.5, 8, 9.3, 9.5, 9.6 and 9.8 - 9.15 (inclusive) shall survive any termination or expiration of this Agreement.

6.4. AMAG's Rights in Bankruptcy. All rights and licenses granted pursuant to any section of this Agreement are, and will be deemed to be, licenses of rights to "intellectual property" (as defined in Section 101(35A) of title 11 of the United States Code, 11 U.S.C. § 101, et seq (the "Bankruptcy Code")) and of any similar provisions of applicable Laws under any other jurisdiction. Access agrees that AMAG, as a licensee of such rights and licenses under this Agreement, will retain and may fully exercise all of its rights and elections under the Bankruptcy Code (including under Section 365(n) of the Bankruptcy Code).

(a) Embodiments of Intellectual Property. AMAG will have all rights to embodiments of the intellectual property licensed to AMAG under this Agreement, as set forth in Section 365(n) of the Bankruptcy Code. AMAG's rights to use and reference Governmental Clearances are essential to its rights to intellectual property and AMAG will retain and may fully exercise all such rights.

(b) Effect of Bankruptcy Filing. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Access under the Bankruptcy Code or analogous provisions of applicable law outside of the United States, then unless or until this Agreement is rejected or deemed rejected, Access or its trustee, pursuant to Section 365(n) of the Bankruptcy Code and upon the written request of AMAG:

- (i) will perform this Agreement; or
- (ii) will deliver all embodiments of such intellectual property, which, if not already in AMAG's possession, will be promptly delivered to it upon AMAG's written request therefor, to the full extent required by Section 365(n)(4) of the Bankruptcy Code.

(c) Reservation of Rights. Nothing in this Section 3.8 will limit or restrict, or will be construed to limit or restrict, the rights of AMAG under Section 365(n) of the Bankruptcy Code, all of which rights are hereby expressly reserved.

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## ARTICLE 7

### REPRESENTATIONS, WARRANTIES, COVENANTS, LIMITATION OF LIABILITY, INDEMNIFICATION

7.1 Access Representations and Warranties. Access represents, warrants and covenants to AMAG as follows:

(a) Access is a corporation duly organized, validly existing and in good standing under the laws of state or jurisdiction in which it is incorporated, and it has full right and authority to enter into this Agreement and to grant the licenses and other rights to AMAG as herein described.

(b) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of Access enforceable against Access in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other law affecting creditors' rights generally from time to time if effect, and to general principles of equity.

(c) The execution, delivery and performance of this Agreement does not conflict with any other agreement, contract, instrument or understanding, oral or written, to which Access is a party, or by which it is bound, nor will it violate any law applicable to Access.

(d) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other persons or entities required to be obtained by Access in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

(e) The Patents identified on Schedule B are all of the Patent Rights Controlled by Access and its Affiliates as of the Effective Date that are necessary or useful for the Manufacture or Commercialization of the Device in the Territory. Access covenants that it will provide updated versions of Schedule B as needed so that such Schedule B is current and complete throughout the Term.

(f) Access and its Affiliates have disclosed or provided to AMAG and its Affiliates access to true and correct copies of all (i) all Governmental Clearances in the Territory, (ii) all safety data relevant to the Device, including all complaints, MedWatch reports and Medical Device Reports (“MDRs”), correction and removal reports and records, and recall records, (iii) all reports, warnings or notices from any and all Governmental Authorities related to the Device in the Territory, (iv) any and all notices from Third Parties regarding infringement or misappropriation of any intellectual property, (v) all non-clinical and clinical data related to the Device, including clinical data from completed, terminated or ongoing clinical trials, whether sponsored by Access or a Third Party, (vi) sales data, including the dates, quantities and prices for which the Device has been sold by or on behalf of Access in the Territory, customer lists, customer contracts, wholesale agreements, distribution agreement, Device Return rates, rebate agreements or policies, standard operating procedures, written policies, Promotional

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Materials, training materials, forms and other relevant commercial records relevant to the Commercialization of the Device in the Territory, and (vii) any other information that would be material to assessing the clinical or commercial potential, or risks of Commercialization of the Device in the Territory.

(g) Neither Access nor any of its Affiliates has previously assigned, transferred, conveyed or otherwise encumbered its right, title and interest in the Access Intellectual Property Rights in a manner inconsistent with the terms hereof. There is no agreement to which Access or any of its Affiliates is a party and by which it is bound that would conflict with or be breached by Access granting AMAG the licenses in Section 2.1 or assigning AMAG the rights assigned under Section 2.2 to AMAG.

(h) Neither Access nor any of its Affiliates are parties to any agreements with any Third Party relating to the Device (“Third Party Agreement(s)”), other than the Third Party Agreements expressly disclosed in Schedule D attached hereto, true and complete copies of which have been provided to AMAG, (i) except as provided in the Third Party Agreements, no Third Party has any right, title or interest in or to, or any license under, any Access Intellectual Property Rights, (ii) no rights granted by or to Access or its Affiliates or any requirements or obligations set forth under any Third Party Agreement conflict with this Agreement or any right or license granted to AMAG or its Affiliates hereunder, (iii) Access and its Affiliates are and at all times have been in compliance in all material respects with all Third Party Agreements, (iv) the Third Party Agreements are in full force and effect and, to its best knowledge, represent valid and enforceable obligations of the applicable Third Parties party thereto, (v) Access will, as set forth in Section 5.1(b): (1) assign to AMAG all of Access’s rights under those Third Party Agreements that are designated “To be Assigned to AMAG” on Schedule D, subject to Access retaining responsibility for any Retained Liabilities associated with such agreements, (2) terminate those Third Party Agreements that are designated “To be Terminated” on Schedule D and (3) continue in effect and for the benefit of AMAG those Third Party Agreements that are designated “To be Maintained” on Schedule D.

(i) Access has no knowledge of any (i) claims, judgments or settlements against Access or its Affiliates pending, or threatened, that invalidate or seek to invalidate the Access Patent Rights; (ii) pending litigation against Access or any Affiliate of Access that alleges that any of Access’s activities relating to the Device have violated or would violate, any of the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation).

(j) Access has no knowledge of any (i) claim, demand, suit, proceeding, arbitration, inquiry, investigation or other legal action of any nature, civil, criminal, regulatory or otherwise, pending or, threatened against Access or any of its Affiliates or (ii) judgment, injunction, consent decree, seizure, detention or settlement against or owed by Access or any of its Affiliates, in each case in connection with the Access Intellectual Property Rights, the Device, Commercialization activities related to

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the Device, Third Party Agreements, or relating to the transactions contemplated by this Agreement.

(k) No royalty, milestone or other payment are or will become payable to any Third Party under any agreement entered into by and among Access or its Affiliates, and any Third Party, in connection with the development, Commercialization or use of the Device under and in accordance with this Agreement by AMAG or its Affiliates or Sublicensees or agents or distributors.

(l) Access and its Affiliates will (i) not amend or otherwise modify any Third Party Agreement or consent or waive rights with respect thereto in any manner that adversely affects (A) the rights granted to AMAG or AMAG's Affiliates or Sublicensees hereunder or (B) Access's ability to fully perform its obligations hereunder without the prior written consent of AMAG (such consent not to be unreasonably withheld or delayed); (ii) promptly furnish AMAG with true and complete copies of all amendments to the Third Party Agreements executed following the Effective Date; (iii) remain, and cause its Affiliates to remain, in compliance in all material respects with all Third Party Agreements; (iv) not terminate, take any action that would result in termination of (or fail to take any action the absence of which would result in termination of) any Third Party Agreement without the prior written consent of AMAG (such consent not to be unreasonably withheld or delayed); and (v) furnish AMAG with copies of all notices received by Access or its Affiliates relating to any alleged breach or default by Access or its Affiliates under any Third Party Agreement within five (5) Business Days after receipt thereof.

(m) Neither Access nor any of its Affiliates shall, directly or with or through any Third Parties, engage in any research and development activities, including any clinical development activities, concerning the Device in the Field: (1) inside the Territory or (2) outside of the Territory to the extent such activities could reasonably be anticipated to have a negative impact on the sale of Device within the Territory, the value of the rights granted hereunder to AMAG or AMAG's ability to exercise such rights.

(n) Access hereby certifies that neither Access, nor any of its employees or agents involved in the research, development or Commercialization of the Device, has (1) ever been, is currently, or is the subject of a proceeding that has lead or could lead to that party becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual or (2) to the knowledge of Access, has engaged in any activities which are prohibited, or are cause for civil penalties, or grounds for mandatory or permissive exclusion, debarment or suspension by any Governmental Authority.

(o) Access is, has been and during the [\*\*\*] Transition Period shall remain in compliance in all material respects with applicable Healthcare Laws and with the applicable policies of healthcare payers and insurers.



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(p) Any and all samples of the Device have been distributed by Access exclusively for purposes of distribution as samples (not for sale or resale) to physicians or other health care professionals permitted to accept and/or receive samples in accordance with the legal requirements applicable to the distribution and provision of samples of the Device, and for no other purpose, and the distribution of such samples has been appropriately documented in compliance with all Applicable Laws. During the [\*\*\*] Transition Period, any and all samples of the Device distributed by Access shall be exclusively for purposes of distribution as samples (not for sale or resale) to physicians or other health care professionals permitted to accept and/or receive samples in accordance with the legal requirements applicable to the distribution and provision of samples of the Device, and for no other purpose, and the distribution of such samples by Access shall be appropriately documented in compliance with all Applicable Laws.

(q) Access has not committed, engaged in or had committed on its behalf or authorized, any activities that would be reportable to any governmental authority under the so-called “sunshine provisions” in the Patient Protection and Affordable Health Care Act. During the [\*\*\*] Transition Period, Access will not commit, engage in or authorize any activities that would be reportable to any governmental authority under the so-called “sunshine provisions” in the Patient Protection and Affordable Health Care Act.

(r) [\*\*\*].

7.2 AMAG Representations and Warranties. AMAG covenants, represents and warrants to Access that as of the Effective Date:

(a) AMAG is a corporation duly organized, validly existing and in good standing under the laws of state in which it is incorporated, and it has full right and authority to enter into this Agreement and to accept the rights and licenses granted as herein described.

(b) This Agreement has been duly authorized by all requisite corporate action, and when executed and delivered will become a valid and binding contract of AMAG enforceable against AMAG in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium and other laws affecting creditors’ rights generally from time to time if effect, and to general principles of equity.

(c) The execution, delivery and performance of this Agreement does not conflict with any other agreement, contract, instrument or understanding, oral or written, to which AMAG is a party, or by which it is bound, nor will it violate any law applicable to AMAG.

(d) All necessary consents, approvals and authorizations of all regulatory and governmental authorities and other persons or entities required to be obtained by AMAG in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

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(e) AMAG hereby certifies that neither AMAG, nor any of its employees or agents that will be involved in the Commercialization of the Device, has ever been, is currently, or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred Entity or Individual, an Excluded Entity or Individual or a Convicted Entity or Individual.

7.3 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH HEREIN, NEITHER ACCESS NOR AMAG MAKES ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT. THE REPRESENTATIONS AND WARRANTIES OF EACH OF ACCESS AND AMAG EXTEND ONLY TO THE OTHER PARTY. NEITHER PARTY WILL BE LIABLE FOR ANY CLAIM OR DEMAND AGAINST SUCH OTHER PARTY BY A THIRD PARTY, EXCEPT TO THE EXTENT PROVIDED IN SECTION 7.5.

7.4 Limitation of Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, NEITHER PARTY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT FOR ANY INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY; PROVIDED, HOWEVER, THAT THIS SECTION 7.4 WILL NOT APPLY TO (a) THE PARTIES' INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTIONS 7.5(a) AND 7.5(b) or BREACH OF CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 8.

#### 7.5 Indemnification.

(a) AMAG Indemnity. AMAG hereby agrees to indemnify and hold Access and its Affiliates, and their respective employees, directors, agents and contractors, and their respective successors, heirs and assigns and representatives ("Access Indemnitees") harmless from and against all claims, liability, threatened claims, damages, expenses (including reasonable attorneys' fees), suits, proceedings, losses or judgments, whether for money or equitable relief, of any kind, including death, personal injury, illness, product liability or property damage or the failure to comply with Applicable Law (collectively, "Losses"), arising from any Third Party claim to the extent due to (i) the Manufacture, Commercialization use or other disposition of the Device by AMAG [\*\*\*], (ii) AMAG's negligence or willful misconduct, or (iii) AMAG's breach of this Agreement, except in each case in the event and to the extent that such Losses arise from (A) the negligence or willful misconduct of Access or (B) any breach of this Agreement by Access.

(b) Access Indemnity. Access hereby agrees to indemnify and hold AMAG, its Affiliates and Sublicensees, and their respective employees, directors, agents and contractors, and their respective successors, heirs and assigns and representatives ("AMAG Indemnitees") harmless from and against all Losses arising from any Third Party claims to the extent due to (i) the Manufacture, Commercialization use or other disposition of the Device by Access [\*\*\*], (ii) the negligence, or willful misconduct of Access or (iii) any breach of this Agreement by Access, except in each case in the event

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and to the extent that such Losses arise from (A) the negligence or willful misconduct of AMAG or (B) any breach of this Agreement by AMAG.

(c) Indemnification Procedure. A claim to which indemnification applies under Section [7.5\(a\)](#) or Section [7.5\(b\)](#) will be referred to herein as a “Claim”. If any person or entity (each, an “Indemnitee”) intends to claim indemnification under this Section [7.5](#), the Indemnitee will notify the other Party (the “Indemnitor”) in writing promptly upon becoming aware of any claim that may be a Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice will not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor will have the right to assume and control the defense of such Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; provided, however, that an Indemnitee will have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of such Claim as aforesaid, the Indemnitee may defend such Claim but will have no obligation to do so. The Indemnitee will not settle or compromise any Claim without the prior written consent of the Indemnitor, and the Indemnitor will not settle or compromise any Claim in any manner which would require any admission by the Indemnitee or impose any obligation on the Indemnitee, without the prior written consent of the Indemnitee, which consent, in each case, will not be unreasonably withheld. The Indemnitee will reasonably cooperate with the Indemnitor at the Indemnitor’s expense and will make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information will be subject to [Article 8](#).

## ARTICLE 8 CONFIDENTIALITY

### 8.1 Confidentiality.

(a) *Confidential Information*. Except as expressly provided herein, each of the Parties agrees that, for itself and its Affiliates, and for as long as this Agreement is in effect and for a period of [\*\*\*] thereafter, a Party and its Affiliates (the “Receiving Party”) receiving Confidential Information of the other Party or its Affiliates (the “Disclosing Party”) will (i) not disclose such Confidential Information to any Third Party without the prior written consent of the Disclosing Party, except for disclosures expressly permitted below, and (ii) not use such Confidential Information for any purpose except those licensed or otherwise authorized or permitted by this Agreement.

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(b) *Exceptions.* The obligations in Section [8.1\(a\)](#) will not apply with respect to any portion of the Confidential Information that the Receiving Party can show by competent proof:

(i) is publicly disclosed by the Disclosing Party, either before or after it is disclosed to the Receiving Party hereunder;

(ii) was known to the Receiving Party or any of its Affiliates, without any obligation to keep it confidential or any restriction on its use, prior to disclosure by the Disclosing Party;

(iii) is subsequently disclosed to the Receiving Party or any of its Affiliates by a Third Party lawfully in possession thereof and without any obligation to keep it confidential or any restriction on its use;

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(iv) is published by a Third Party or otherwise becomes publicly available or enters the public domain, either before or after it is disclosed to the Receiving Party; or

(v) has been independently developed by employees or contractors of the Receiving Party or any of its Affiliates without the aid, application or use of Confidential Information of the Disclosing Party.

(c) *Authorized Disclosures.* The Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:

(i) subject to Section [8.2](#), by either Party in order to comply with Applicable Law (including any regulations promulgated by the FDA, any securities laws or regulations or the rules of a securities exchange) and with judicial process, if in the reasonable opinion of the Receiving Party's counsel, such disclosure is necessary for such compliance;

(ii) by either Party, in connection with prosecuting or defending litigation, making regulatory filings, and filing, prosecuting and enforcing patent applications and patents; and

(iii) by AMAG, to its Affiliates, potential and future collaborators (including Sublicensees), permitted acquirers or assignees

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under Section [9.1](#), subcontractors, investment bankers, investors, lenders, and each of their respective directors, employees, contractors and agents;

provided that (1) with respect to Section [8.1\(c\)\(i\)](#) or [8.1\(c\)\(ii\)](#), where reasonably possible and to the extent not prohibited by Applicable Law, the Receiving Party will notify the Disclosing Party of the Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow the Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to Section [8.1\(c\)\(iii\)](#), each of those named people and entities must be bound prior to disclosure by confidentiality and non-use restrictions at least as restrictive as those contained in this [Article 8](#) (other than investment bankers, investors and lenders, who must be bound prior to disclosure by commercially reasonable obligations of confidentiality).

**8.2 [Terms of this Agreement](#).** The Parties agree that the terms of this Agreement shall be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section [8.1\(c\)\(i\)](#) or as otherwise provided herein.

**8.3 [Clinical Trial Results](#).** Notwithstanding any other provision of this Agreement, the Parties agree that AMAG may publish summaries of the results of all non-clinical and clinical trials conducted by or on behalf of either Party, pertaining to the Device, and that Access shall not make, and shall not permit any other Person to make, any such publications or disclosure, without the prior written consent of AMAG, such consent not to be unreasonably withheld. AMAG shall provide Access with an advance copy of any such publication and will consider in good faith any comments relating thereto provided by Access within seven (7) Business Days after receipt by Access of the advance copy from AMAG.

**8.4 [Press Releases and Public Disclosures](#).** Each Party agrees to coordinate timing of and not to issue any press release or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby without the prior written consent of the other Party, other than with respect to the terms and conditions of this Agreement in accordance with Section 8.4, provided, however, that any disclosure which is required by Applicable Law (including the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended), or the rules of a securities exchange or the Securities and Exchange Commission or the securities regulators of any state or other jurisdiction, as reasonably advised by the disclosing Party's counsel, may be made subject to the following. The Parties agree that any such required disclosure will not contain confidential business or technical information and, if disclosure of confidential business or technical information is required by Applicable Law or such rules or regulators, the Parties will use appropriate diligent efforts to minimize such disclosure and obtain confidential treatment for any such information which is disclosed to a governmental agency. Each Party agrees to provide to the other Party a copy of any public announcement regarding this Agreement or the subject matter thereof as soon as reasonably practicable under the circumstances prior to its scheduled release. Except under extraordinary circumstances, each Party shall provide the other with an advance copy of any such announcement at least two (2) Business Days prior to its scheduled release. Each Party shall have the right to expeditiously

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review and recommend changes to any such announcement and, except as otherwise required by Applicable Law or such rules or regulators, the Party whose announcement has been reviewed shall remove any Confidential Information of the reviewing Party that the reviewing Party reasonably deems to be inappropriate for disclosure. The contents of any announcement or similar publicity that has been reviewed and approved by the reviewing Party can be re-released by either Party without a requirement for pre-approval.

## **ARTICLE 9 GENERAL PROVISIONS**

9.1 Assignment. Neither Party may assign this Agreement, delegate its obligations or otherwise transfer licenses or other rights created by this Agreement, without the prior written consent of the other Party, which consent will not be unreasonably withheld; provided that each Party may assign this Agreement as a whole without such consent in connection with the acquisition (whether by merger, consolidation, sale or otherwise) of such Party, provided that such Party provides written notice to the other Party of such assignment and the assignee thereof agrees in writing to be bound as such Party hereunder. Any assignment or transfer in violation of this Section [9.1](#) will be void. This Agreement will inure to the benefit of, and be binding upon, the legal representatives, successors and permitted assigns of the Parties.

9.2 Force Majeure. Neither Party will be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term or condition of this Agreement if, but only to the extent that, such failure or delay results from causes beyond the reasonable control of the affected Party, potentially including fire, floods, embargoes, terrorism, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any Governmental Authority or any other Party; provided that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.

9.3 Severability. If any one or more of the provisions contained in this Agreement is held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affects the substantive rights of the Parties. The Parties will in such an instance use their reasonable best efforts to replace the invalid, illegal or unenforceable provision(s) with valid, legal and enforceable provision(s) which, insofar as practical, implement the purposes of this Agreement.

9.4 Amendment; Waiver. This Agreement may not be modified, amended or rescinded, in whole or part, except by a written instrument signed by the Parties; provided that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. No delay or omission by either Party hereto in exercising any right or power occurring upon any noncompliance or default by the other Party with respect to any of the terms of this Agreement will impair any such right or power or be construed to be a waiver thereof. A waiver by either of

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the Parties of any of the covenants, conditions or agreements to be performed by the other will not be construed to be a waiver of any succeeding breach thereof or of any other covenant, condition or agreement herein contained.

9.5 Notices. Except as otherwise provided herein, all notices under this Agreement will be sent by certified mail or by overnight courier service, postage prepaid, to the following addresses of the respective Parties:

If to AMAG, to:                   AMAG Pharmaceuticals, Inc.  
100 Hayden Ave.  
Lexington, MA 02421  
Attn.: Chief Executive Officer

With a required copy to:       AMAG Pharmaceuticals, Inc.  
100 Hayden Ave.  
Lexington, MA 02421  
Attn.: General Counsel

If to Access, to:                Access Pharmaceuticals, Inc.  
2600 Stemmons Freeway  
Suite 176  
Dallas TX 75207  
Attn.: Chief Executive Officer

or to such address as each Party may hereafter designate by notice to the other Party. A notice will be deemed to have been given on the date it is received by all required recipients for the noticed Party.

9.6 Applicable Law, Venue. This Agreement will be governed by and construed in accordance with the laws of the New York, without reference to conflicts of laws principles. Notwithstanding the foregoing, with respect to any dispute relating to the determination of scope, validity or enforceability of any Patents, the Parties consent to the exclusive jurisdiction of the Federal courts of the United States, and the dispute shall be determined according to the laws of the United States. The Parties hereby expressly agree that the U.N. Convention on Contracts for the International Sale of Goods will not apply. Subject to Section 9.15, the Parties hereby agree to the exclusive jurisdiction of the competent courts sitting in the New York.

9.7 Further Assurances. Each Party agrees to do and perform all such further acts and things and will execute and deliver such other agreements, certificates, instruments and documents necessary or that the other Party may deem advisable in order to carry out the intent and accomplish the purposes of this Agreement and to evidence, perfect or otherwise confirm its rights hereunder.

9.8 Relationship of the Parties. Each Party is an independent contractor under this Agreement. Nothing contained herein is intended or is to be construed so as to constitute Access and AMAG as partners, agents or joint venturers. Neither Party will have any express or implied

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right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party. There are no express or implied third party beneficiaries hereunder.

9.9 Entire Agreement. This Agreement (along with the Exhibits) contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes and replaces any and all previous or contemporaneous arrangements and understandings, whether oral or written, between the Parties with respect to the subject matter hereof.

9.10 Headings. The captions to the several Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Sections hereof.

9.11 Waiver of Rule of Construction. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement will be construed against the drafting party will not apply.

9.12 Interpretation. Whenever any provision of this Agreement uses the term “including” (or “includes”), such term will be deemed to mean “including without limitation” (or “includes without limitations”). “Herein,” “hereby,” “hereunder,” “hereof” and other equivalent words refer to this Agreement as an entirety and not solely to the particular portion of this Agreement in which any such word is used. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Unless otherwise provided, all references to Sections and Exhibits in this Agreement are to Sections and Exhibits of this Agreement. References to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered “Section 3(a)” would be part of [Article 3](#)”, and references to “Section 3” would also refer to material contained in the subsection described as “Section 3(a)”).

9.13 Counterparts; Facsimiles. This Agreement may be executed in two or more counterparts, each of which will be deemed an original and all of which together will constitute one and the same instrument. Facsimile execution and delivery of this Agreement by either Party will constitute a legal, valid and binding execution and delivery of this Agreement by such Party

9.14 Issue Resolution. Unless otherwise set forth in this Agreement or the Escrow Agreement, in the event of a dispute arising under this Agreement between the Parties (but not including a dispute relating to the Escrow Agreement which shall be governed by such Escrow Agreement), the Parties shall refer such dispute to the Chief Business Officer of AMAG (or other executive designated by the Chief Executive Officer of AMAG) and the Chief Executive Officer of Access (the “Executive Officer(s)”), and such Executive Officers shall attempt in good faith to resolve such dispute. If the Parties are unable to resolve a given dispute pursuant to this Section 9.14 within sixty (60) days of referring such dispute to the Executive Officers, such dispute shall be resolved by binding arbitration in the manner described in Section 9.15.

9.15 Arbitration.

(a) If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement after the provisions of Section 9.14 have been exhausted (but not including a dispute



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relating to the Escrow Agreement which shall be governed by such Escrow Agreement), such Party shall provide written notice (the "Arbitration Request") to the other Party of such intention and the issues for resolution. From the date of the Arbitration Request and until such time as the dispute has become finally settled, the running of the time periods as to which a Party must cure a breach of this Agreement becomes suspended as to the subject matter of the dispute. Unless the Parties otherwise agree in writing, during the period of time that any arbitration proceeding is pending under this Agreement, the Parties shall continue to comply with all those terms and provisions of this Agreement that are not the subject of the pending arbitration proceeding. The arbitration proceeding shall be conducted in accordance with the Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes of the American Arbitration Association (the "AAA") and otherwise as set forth in this Section 9.15.

(b) Within ten (10) Business Days after the receipt of the Arbitration Request, the other Party may, by written notice, add additional issues for resolution; provided, that such issues have been subject to Section 9.14 and relate directly to the matter that is the subject of the applicable Arbitration Request.

(c) The arbitration shall be conducted by one arbitrator selected in accordance with the AAA Commercial Arbitration Rules and Supplementary Procedures for Large Complex Disputes as modified below, unless the matter in dispute has a value of at least [\*\*\*] and either Party wishes to have the arbitration conducted by a panel of three (3) arbitrators. The arbitrator(s) shall be experienced in the subject matter of the Arbitration Request as it applies to the biotechnology or pharmaceutical business. The Parties shall cooperate to attempt to select the arbitrator(s) by agreement within twenty (20) days of the initiation of arbitration. If agreement cannot be reached within such twenty (20) days, then that AAA will submit a list of twenty (20) qualified arbitrators from which each Party shall strike unacceptable entries; provided that each Party shall not strike more than thirty-five percent (35%) of the names without cause, and rank the remaining names. The AAA shall appoint the arbitrator(s) with the highest combined ranking(s). If these procedures fail to result in selection of the required number of arbitrators, the AAA shall appoint the arbitrator(s), allowing each side challenges for cause. The arbitrator(s) shall apply the law of New York and the arbitration shall be held in New York, New York. The Parties shall each use their best efforts to have the arbitration hearing held as soon as practicable and in any event within sixty (60) days after the selection of the arbitrator(s). At least five (5) Business Days prior to the arbitration hearing, each Party shall submit to the other Party and the arbitrator(s) a copy of all exhibits on which such Party intends to rely at the hearing, a pre-hearing brief (up to 20 pages), and a proposed ruling (up to 5 pages). The proposed ruling shall be limited to proposed rulings and remedies on each issue, and shall contain no argument on or analysis of the facts or issues. Within five (5) Business Days after close of the hearing, each Party may submit a post-hearing brief (up to 5 pages) to the arbitrator(s).

(d) Either Party may apply first to the arbitrators for interim injunctive relief until the arbitration decision is rendered or the arbitration matter is otherwise resolved; provided, that if such Party determines that such injunctive relief cannot be awarded in a timeframe adequate to protect such Party's interests, then a Party may, without waiving any right or remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary

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to protect the rights or property of that Party pending resolution of the arbitration matter pursuant to this Section 9.15. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's compensatory damages. The Parties further agree that the decision of the arbitrators shall be the sole, exclusive and binding remedy between them regarding determination of arbitration matters presented.

(e) The Parties hereby agree that any disputed performance or suspended performance pending the resolution of an arbitration matter that the arbitrators determine to be required to be performed by a Party must be completed within a reasonable time period following the final decision of the arbitrators.

(f) [\*\*\*].

(g) Except to the extent necessary to confirm an award or decision or as may be required by Applicable Laws, neither a Party nor an arbitrator may disclose the existence, content, or results of an arbitration without the prior written consent of both Parties.

(h) The Parties agree that, in the event of an arbitration matter involving the alleged breach of this Agreement, neither Party may terminate this Agreement until resolution of such matter pursuant to this Section 9.15, and any time period for cure will only commence after such resolution.

(i) By agreeing to this binding arbitration provision, the Parties understand that they are waiving certain rights and protections which may otherwise be available if a dispute between the Parties were determined by litigation in court, including the right to seek or obtain certain types of damages precluded by this provision, the right to a jury trial, certain rights of appeal, and a right to invoke formal rules of procedure and evidence.

(j) For avoidance of doubt, any dispute between the Parties relating to the Escrow Agreement or the [\*\*\*] shall be governed by the dispute resolution provisions set forth in the Escrow Agreement.

*[Remainder of this page is intentionally left blank ]*

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**SIGNATURE PAGE TO LICENSE AGREEMENT**

In Witness Whereof, this Agreement has been executed by the Parties as of the Effective Date.

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**AMAG PHARMACEUTICALS, INC.**

By: /s/ William K. Heiden

Name: William K. Heiden

Title: President and Chief Executive Officer

**ACCESS PHARMACEUTICALS, INC.**

By: /s/ Jeffrey B. Davis

Name: Jeffrey B. Davis

Title: Chief Executive Officer

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## **SCHEDULE A**

### **Defined Terms**

(b) “AAA” has the meaning ascribed to it in Section 9.15

(c) “Access” has the meaning provided in the introductory paragraph above.

(d) “Access Know-How” means all Technology, now existing or hereafter arising that is Controlled by Access, and that is related to the Device or that is necessary or useful for the Manufacture or Commercialization of the Device.

(e) “Access Indemnitees” has the meaning provided in Section 7.5(a).

(f) “Access Intellectual Property Rights” means, collectively, the Access Know-How, the Access Patent Rights, and the Access Trademarks.

(g) “Access Patent Rights” means Patents Controlled by Access during the Term that are necessary or useful for the Manufacture or Commercialization of the Device. The Access Patent Rights in existence as of the Effective Date are identified in Schedule B, attached hereto.

(h) “Access Trademarks” means the marks identified in Schedule C, attached hereto.

(i) “Affiliates” means any entity controlling, controlled by or under common control with a Party, but only as long as such control continues, where “control” means the ownership of at least fifty percent (50%) of the equity or beneficial interest of such entity, or the right to vote for or appoint a majority of the board of directors or other governing body of such entity.

(j) “Agreement” has the meaning provided in the introductory paragraph above.

(k) “AMAG” has the meaning provided in the introductory paragraph above.

(l) “AMAG Indemnitees” has the meaning provided in Section 7.5(b).

(m) “Applicable Law” means any supra-national, federal, state, provincial, commonwealth, cantonal or local government laws, treaties, statutes (including the Food, Drug and Cosmetic Act of 1938, as amended), rules and regulations, including any rules, regulations, guidance or guidelines having the binding effect of law,

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or requirements of Governmental Authorities, national securities exchanges or securities listing organizations, courts, tribunals, legislative bodies and commissions that may be in effect from time to time.

(n) “Arbitration Request” has the meaning ascribed to it in Section 9.15

(o) “[\*\*\*]” has the meaning provided in [\*\*\*].

(p) “Auditor” has the meaning ascribed to it in Section 3.8.

(q) “Bankruptcy Code” has the meaning provided in Section 6.4.

(r) “Business Day” means a day other than Saturday, Sunday or any day on which commercial banks located in New York, New York are authorized or obligated by Applicable Law to close.

(s) “Claim” has the meaning provided in Section 7.5(c).

(t) “Commercially Reasonable Efforts” means, with respect to any objective related to the Manufacturing and Commercialization of the Device, efforts and resources that a company within the same industry would reasonably devote to a medical device owned by it which is of similar market potential at a similar stage in the development or life of such product, taking into account issues of safety and efficacy, device profile, the proprietary position of the device, the then current competitive environment for such medical device, the likely timing of such medical device’s entry into the market, the regulatory environment and status of such medical device, the profitability of the medical device and other relevant commercial factors.

(u) “Commercialization” or “Commercialize” means activities directed to the marketing, promoting, distributing, importing, exporting, offering for sale or selling a Device.

(v) “Commercialization Plan” has the meaning ascribed to it in Section 2.5.

(w) “Competitive Device” has the meaning provided in Section 2.3.

(x) “Confidential Information” means all confidential or proprietary information including information comprising or relating to the activities conducted pursuant to this Agreement, that is disclosed or provided by a Party or its Affiliates to the other Party or its Affiliates, regardless of whether any of the foregoing are marked ”confidential” or ”proprietary” or communicated to the other by the disclosing Party or its Affiliates in oral, written, graphic, or electronic form.

(y) “[\*\*\*]” has the meaning ascribed to it in [\*\*\*].

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(z) “Control” means, with respect to any material, information or intellectual property right, that a Party owns or has a license or other legal right and ability to grant to the other Party an option, access, a license or a sublicense (as applicable) on the terms and conditions set forth herein without violating the terms of any agreement or other arrangement with any Third Party applicable to such material, information or intellectual property right and existing at the time such option, access, license or sublicense, as applicable, is granted.

(aa) “Convicted Individual” or “Convicted Entity” means an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

(bb) “Customer” means Third Parties (e.g., wholesalers, specialty pharmacies, etc.) to whom Access or its Affiliates or Sublicensees have sold Devices.

(cc) “Debarred Individual” means an individual who has been debarred by the U. S. Food and Drug Administration (“FDA”) pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a person that has an approved or pending drug product application.

(dd) “Debarred Entity” means a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(ee) “Device” means the MuGard™ device, a viscous, mucoadhesive rinse that is based on Access Intellectual Property Rights, in any dosage form, formulation and form of administration for use in the Field.

(ff) “Device Returns” means any Devices that have been sold or otherwise used and that have been sent back to AMAG for any reason.

(gg) “Disclosing Party” has the meaning provided in Section 8.1(a).

(hh) “Diverted Product” has the meaning provided in Section 2.4.

(ii) “Effective Date” has the meaning provided in the introductory paragraph above.

(jj) “Escrow Agent” has the meaning provided in Section 4.1(d).

(kk) “Escrow Agreement” has the meaning provided in Section 4.1(d).

(ll) “Excess Load In Charge” has the meaning ascribed to it in Section 5.1(a).

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(mm) “Excluded Individual” or “Excluded Entity” means (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (ii) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration.

(nn) “Executive Officers” has the meaning ascribed to it in Section 9.14.

(oo) “FDA” means the United States Food and Drug Administration of the Department of Health and Human Services, or any successor agency(ies).

(pp) “[\*\*\*]” has the meaning ascribed to it in [\*\*\*].

(qq) “[\*\*\*]” has the meaning ascribed to it in [\*\*\*].

(rr) “Field” has the meaning ascribed to it in Section 2.1.

(ss) “First Commercial Sale” means, with respect to the Device, the first transfer by AMAG or any of its Affiliates or Sublicensees for value in an arms’-length transaction to an independent Third Party distributor, agent or end user in the Territory after obtaining [\*\*\*] necessary for such transfer and to commence regular commercial sales in the United States.

(tt) “[\*\*\*]” has the meaning ascribed to it in [\*\*\*].

(uu) “Governmental Authority” means any and all governmental and regulatory authorities having jurisdiction over the Device in the Territory, or over any performance or obligations associated with this Agreement, including but not limited to the FDA or any other successor entities thereto.

(vv) “Governmental Clearances” means any and all permits, licenses, authorizations, and clearances, including Regulatory Clearances required by any Governmental Authority for the manufacture, importation, marketing and selling of the Device in the Territory.

(ww) “Healthcare Law” means the laws, codes, policies and guidelines of all Governmental Authorities relating to the production, preparation, propagation, compounding, conversion, pricing, marketing, promotion, sale, distribution, coverage, or reimbursement of a drug, device, biological or other medical item, supply or service, including, without limitation, the federal Food, Drug and Cosmetic Act (21 U.S.C. § 321 et seq.), the federal False Claims Act (31 U.S.C. §§ 3729 et seq.), the federal healthcare program anti-kickback statute (42 U.S.C. § 1320a-7b), the healthcare fraud, false statement and health information privacy and security provisions of the Health Insurance



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Portability and Accountability Act of 1996 (“HIPAA”), as amended by the Health Information Technology for Economic and Clinical Health (“HITECH”) Act, the Foreign Corrupt Practices Act, the U.K. Anti-Bribery Act, the federal healthcare program civil money penalty and exclusion authorities, the applicable requirements of Medicare, Medicaid and other Governmental Body healthcare programs, including the Veterans Health Administration and U.S. Department of Defense healthcare and contracting programs, and the analogous Laws of any state or country applicable to the Agreement.

(xx) “Indemnitee” has the meaning provided in Section 7.5(c).

(yy) “Indemnitor” has the meaning provided in Section 7.5(c).

(zz) “[\*\*\*]” has the meaning ascribed to it in [\*\*\*].

(aaa) “Inventory” has the meaning provided in Section 5.1(c).

(bbb) “Losses” has the meaning provided in Section 7.5(a).

(ccc) “Manufacturing” means any and all activities related to the production of a Device Commercialized under this Agreement. Manufacturing shall include: (i) technical and process development activities in connection with development of the manufacturing or production process for the Device; (b) manufacturing and production activities; (iii) quality assurance activities; (d) testing activities, including stability testing and conformance testing; and (v) any and all other activities required to release manufacturing lots of Devices. When used as a verb, Manufacture means to engage in Manufacturing.

(ddd) “[\*\*\*] Transition Period” has the meaning ascribed to it in Section 5.1(b).

(eee) “MDRs” has the meaning ascribed to it in Section 7.1(f).

(fff) “Net Sales” means the gross amount invoiced for sales of the Device by AMAG, its Affiliates and any Sublicensees to a Third Party distributor or agent (in each case, who is not a Sublicensee), or end user less the following amounts, to the extent actually incurred or accrued, related to the Device:

[\*\*\*].

(ggg) “Parties” has the meaning provided in the introductory paragraph above.

(hhh) “Party” has the meaning provided in the introductory paragraph above.

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(iii) “Patent” means patents and patent applications Controlled by Access or its Affiliates and licensed to AMAG hereunder, in the Territory, including any divisionals, continuations, continuations-in-part, substitutions, reissues, re-examinations, revalidations, patent term extensions, and renewals of any such patents or patent applications, that claim or cover the Device or Commercialization thereof.

(jjj) “Person” means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, Governmental Authority, or other entity or organization.

(kkk) “Promotional Materials” has the meaning provided in Section 6.3(b).

(lll) “Quality Agreement” has the meaning provided in Section 5.1(f).

(mmm) “Quality and Supply Agreements” has the meaning provided in Section 5.1(f).

(nnn) “QSR” has the meaning provided in Section 4.3(a).

(ooo) “Receiving Party” has the meaning provided in Section 8.1(a).

(ppp) “Regulatory Clearance” means the 510(k) clearance for the Device, and any other clearance or approval that is necessary to allow the Device to be marketed and sold in the Territory.

(qqq) “Release Event” has the meaning ascribed to it in Section 4.9(c).

(rrr) “Retained Sales” has the meaning provided in Section 5.1(a).

(sss) “Retained Liabilities” has the meaning provided in Section 5.1(a).

(ttt) “Royalty Term” has the meaning provided in Section 3.3.

(uuu) “Second Source” has the meaning provided in Schedule E.

(vvv) “[\*\*\*]” has the meaning provided in [\*\*\*].

(www) “Specifications” has the meaning provided in Schedule E.

(xxx) “Specified Event” has the meaning provided in Section 4.9.

(yyy) “Sublicensee” means any Person to whom AMAG grants a sublicense of the rights and licenses granted to AMAG by Access under Section 2.1, excluding Persons that are granted such a sublicense solely to perform services for the benefit of AMAG or an Affiliate of AMAG and are not granted any rights to make use or sell Devices to any other Person, including contract manufacturers.

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(zzz) “Supply Agreement” has the meaning provided in Section 5.1(f).

(aaaa) “Technology” means know-how, trade secrets, chemical and biological materials, formulations, information, documents, studies, results, data and regulatory approvals, data, filings and correspondence, including biological, chemical, pharmacological, toxicological, pre-clinical, clinical and assay data, manufacturing processes and data, specifications, sourcing information, assays, and quality control and testing procedures, whether or not patented or patentable.

(bbbb) “Term” has the meaning provided in Section 6.1.

(cccc) “Territory” means the fifty states of the United States of America, its territories and possessions, including the Commonwealth of Puerto Rico, and the District of Columbia.

(dddd) “Third Party” means any Person other than AMAG, Access and their Affiliates.

(eeee) “Third Party Agreements” has the meaning provided in Section 7.1(h).

(ffff) “Valid Claim” means any claim of an issued and unexpired Patent that (a) has not been held permanently revoked, unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal and (b) has not been abandoned, disclaimed, surrendered or declared invalid or unenforceable in a final, unappealable or unappealed decision of a judicial or administrative court, government agency or patent office of appropriate jurisdiction.

(gggg) “[\*\*\*]” has the meaning ascribed to it in Section 4.9(c).

*[Remainder of this page is intentionally left blank ]*

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**SCHEDULE B**

**Access Patent Rights**

U.S. Patent #7,547,433

U.S. Patent #7,544,348

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## SCHEDULE C

### Access Trademarks

# MuGard

Word Mark	MUGARD
Goods and Services	IC 005. US 006 018 044 046 051 052. G & S: Pharmaceutical preparations for the prevention and treatment of disorders of the nervous system, the immune system, the cardio-vascular system, the metabolic system, the respiratory system, the musculo-skeletal system, the genitourinary system; for the treatment of inflammatory disorders; for use in dermatology, oncology, hematology and in tissue and organ transplantation, in ophthalmology and for gastroenterological disorders; Pharmaceutical preparations for the prevention and treatment of ocular disorders or diseases, for the treatment of bacteria-based diseases, and for the treatment of diabetes, and anti-infective preparations, antiviral preparations, antibiotics, antifungal preparations and vaccines; Pharmaceutical preparations for the treatment and prevention of oral and esophageal mucositis; drug delivery agents consisting of compounds that facilitate delivery of a wide range of active pharmaceuticals to the oral mucosa. FIRST USE: 20061225. FIRST USE IN COMMERCE: 20061225
Standard Characters Claimed	
Mark Drawing Code	(4) STANDARD CHARACTER MARK
Serial Number	85116721
Filing Date	August 26, 2010
Current Basis	1A
Original Filing Basis	1A
Published for Opposition	February 8, 2011
Registration Number	3950832
Registration Date	April 26, 2011
Owner	(REGISTRANT) Access Pharmaceuticals CORPORATION DELAWARE 2600 Stemmons Parkway, Suite 176 Dallas TEXAS 75207
Type of Mark	TRADEMARK
Register	PRINCIPAL
Live/Dead Indicator	LIVE

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**SCHEDULE D**

**Third Party Agreements**

**A. To be Assigned to AMAG**

[\*\*\*]

**B. To be Assigned Upon Amendment signed by Counter-Party**

[\*\*\*]

[\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

**C. To be Maintained by Access**

[\*\*]

**D. To be Terminated by Access**

[\*\*]

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## **SCHEDULE E**

### **Quality and Supply Agreements Terms**

This Schedule E describes the basic scope and principles to be included in the Quality and Supply Agreements, which will govern supply of AMAG requirements of the Device pursuant to the terms of Article 5.1(f) of the License Agreement. Capitalized terms used but not defined in this Schedule E shall have the meanings provided in the Agreement.

#### **Scope**

- 1) This Schedule E is not intended to include all terms and conditions anticipated to be included in the Quality and Supply Agreements. The Quality and Supply Agreement will describe and define the procedures, terms and conditions for forecasting, manufacture, analytical testing, quality assurance, delivery, price, payment and appropriate other activities relating to the supply of the Device in the Field and in the Territory consistent with the terms described below and will contain such other terms and conditions customarily contained in supply agreements in the pharmaceutical industry, including without limitation warranties and indemnities.

#### **General**

- 2) AMAG shall purchase from and Access shall supply to AMAG the Device in finished form for use under the Agreement and in accordance with the terms of the Supply Agreement and the Quality Agreement.
- 3) The term of the Supply Agreement and the Quality Agreement shall be coextensive with the Term of the Agreement.
- 4) Access shall use Commercially Reasonable Efforts to manage AMAG's supply needs (e.g., volumes and unit costs) for the Territory in a manner proportionate to Access' supply needs outside the Territory.

#### **Price/ Payment**

- 5) The purchase price for supply of Device shall be the cost thereof actually paid by Access to its Third Party supplier(s) plus [\*\*\*]. Access shall use Commercially Reasonable Efforts to manage purchase price for supply of Device in accordance with its existing agreement with the contract manufacturing organization.
- 6) Payment terms are net [\*\*\*] from receipt of invoice to be issued after shipment.
- 7) Access shall obtain AMAG's prior written consent regarding any capital equipment proposed to be acquired for use in supplying Device to AMAG and for which AMAG would bear all or some portion of the costs. If any such equipment



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is attributable to both the Territory and outside the Territory, the Parties will use good faith efforts to agree on a reasonable allocation of such expenditures to the Territory and outside the Territory, based on the volumes supplied for each such territory. The Supply and Quality Agreements will include a mechanism for resolving any disagreement between the Parties as to the acquisition of any such equipment and/or the allocation between the Parties of the expenditure.

### **Forecasting and Ordering**

- 8) The Supply Agreement will contain mutually agreed information sharing and planning procedures with respect to the forecasting and supply of the Device.

### **Delivery**

- 9) Delivery requirements, location and applicable Incoterms shall be defined in the Supply Agreement.

### **Quality Agreement and Manufacture and Quality Control**

- 10) The parties will enter into a quality agreement within one month after the Effective Date in accordance with the Agreement.
- 11) Device shall be manufactured in compliance with cGMP, as defined by regulatory authorities within the Territory. The Device shall be manufactured according to specifications for the Device set forth in the Quality Agreement ("Specifications").
- 12) The Quality Agreement will contain change control procedures for the Specifications and other related matters.
- 13) The Quality Agreement shall define a procedure for resolution of any disputes regarding product quality.
- 14) In accordance with Section 4.5 of the Agreement, each Party will have a reciprocal audit right allowing, during regular business hours, reasonable access by the other Party's quality assurance, quality control, compliance and other relevant personnel (including the other Party's consultants who are under the same confidentiality and limited use obligations under this Agreement), upon reasonable notice, to audit its facilities and/or its contract manufacturing/laboratory sites where the Device is manufactured, packaged, labeled and/or tested, and shall allow reasonable access to related documentation. The purpose of such audit shall be to assess compliance with the cGMP and applicable Laws in the country of manufacture in accordance with Section 4.5 of the Agreement.

### **Second Source / Safety Stock**

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- 15) The Supply Agreement will contain procedures for implementing a second source of supply (a “ Second Source”).
- 16) AMAG shall [\*\*\*] associated with qualifying, initiating and maintaining the second source of supply (the “[\*\*\*]”). If Access desires to make use of the Second Source for supply needs outside the Territory, the Parties shall use good faith efforts to agree on a [\*\*\*], based on the volumes supplied for each such territory.

### **Product Warranty**

- 17) Access will provide standard warranties including warranties that all Devices:
  - i) shall be manufactured and tested (while in the possession or control of Access, including its third party contract manufacturer) in accordance with all applicable laws, rules, regulations or guidelines of any relevant Regulatory Authority in the United States or any jurisdiction where Access is having Devices manufactured for AMAG, and GMPs applicable to the manufacture, storage, and shipment of Devices,
  - ii) shall not be adulterated or misbranded within the meaning of the United States Food, Drug and Cosmetic Act, 21 U.S.C. Section 301c et. seq., or other applicable laws, rules, regulations or guidelines of any relevant Regulatory Authority in the United States or any jurisdiction where Access is having Devices manufactured for AMAG,
  - iii) conforms to the Specifications, and
  - iv) will have a shelf life of no less than [\*\*\*] from the date of shipment.

This warranty does not apply to any non-conformity of the Device resulting from (i) alteration, misuse, negligence, abuse, accident, mishandling or storage in an improper environment in each case by any party other than Access or its agents or (ii) use, handling, storage or maintenance other than in accordance with the Specifications. THE FOREGOING WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY GIVEN BY ACCESS WITH RESPECT TO THE DEVICE, AND ACCESS GIVES AND MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

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**SCHEDULE F**

**Form of [\*\*\*] Letter  
(attached)**

[\*\*\*]

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**SCHEDULE G**

**Form of \*\*\* Letter**

\*\*\*

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**SCHEDULE H**

**Form of Escrow Agreement**

**(attached)**

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## Three-Party Escrow Service Agreement

### 1. Introduction

This Three-Party Escrow Service Agreement (the “**Agreement**”) is entered into by and between Access Pharmaceuticals, Inc. (the “**Depositor**”), AMAG Pharmaceuticals, Inc. (the “**Beneficiary**”) and \_\_\_\_\_ (“**Escrow Agent**”). Depositor, Beneficiary, and Escrow Agent may be referred to individually as a “Party” or collectively as the “Parties” throughout this Agreement.

- (a) The use of the term services in this Agreement shall refer to Escrow Agent services that facilitate the creation, management, and enforcement of escrow accounts as described in Exhibit A attached hereto (“**Services**”). A Party shall request Services under this Agreement by submitting a work request for certain Escrow Agent Services (“**Work Request**”) via written instruction or the online portal maintained at the website located at \_\_\_\_\_ .com or other websites owned or controlled by Escrow Agent that are linked to that website (collectively the “**Escrow Agent Website**”).
- (b) The Beneficiary and Depositor have entered into a License Agreement dated June \_\_, 2013 (the “**License Agreement**”). The License Agreement conveys certain licenses and rights to the Beneficiary, and the Parties intend this Agreement to be considered as supplementary to the License Agreement, pursuant to Title 11 United States Code, Section 365(n).

### 2. Depositor Responsibilities and Representations

- (a) Depositor shall make a deposit of [\*\*\*] (“**Deposit Material**”) to Escrow Agent within [\*\*\*] of the Effective Date.
- (b) Depositor represents that it lawfully possesses all Deposit Material provided to Escrow Agent under this Agreement and that any current or future liens or encumbrances will not prohibit, limit, or alter the rights and obligations of Escrow Agent under this Agreement. Depositor warrants that with respect to the Deposit Material, Escrow Agent’s proper administration of this Agreement will not violate the rights of any third parties.

### 3. Beneficiary Acknowledgement

- (a) Beneficiary acknowledges that, as between Escrow Agent and Beneficiary, Escrow Agent’s obligation is to maintain the Deposit Material as delivered by the Depositor.

### 4. Escrow Agent Responsibilities and Representations

- (a) Escrow Agent will follow the provisions of Exhibit C attached hereto in administering the release of Deposit Material.
- (b) Escrow Agent will hold and protect Deposit Material in physical vaults that are either owned or under the control of Escrow Agent, unless otherwise agreed to by all the Parties.
- (c) Should transport of Deposit Material be necessary in order for Escrow Agent to perform services requested by Depositor or Beneficiary under this Agreement, Escrow Agent will use a commercially recognized overnight carrier such as Federal Express or United Parcel Service. Escrow Agent will not be responsible for any loss or destruction of, or damage to, such Deposit Material while in the custody of the common carrier.

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**5. Payment**

Beneficiary shall pay to Escrow Agent all Service Fees as set forth herein. [Description of fees to be inserted here (the “Service Fees”).] All Service Fees are due within thirty (30) calendar days from the date of invoice in U.S. currency and are non-refundable.

**6. Term and Termination**

(a) The term of this Agreement is for a period of one (1) year from the Effective Date (“ **Initial Term**”) and will automatically renew for additional one (1) year terms (“**Renewal Term**”) (collectively the “**Term**”). This Agreement shall continue in full force and effect until one of the following events occurs: (i) Depositor and Beneficiary provide Escrow Agent with sixty (60) days’ prior written notice pursuant to a document that is executed by both Beneficiary and Depositor indicating their intent to terminate this Agreement; (ii) Beneficiary provides Escrow Agent and Depositor with sixty (60) days’ prior written notice of Beneficiary’s intent to terminate this Agreement; or (iii) the Agreement terminates under another provision of this Agreement.

**7. Warranties**

(a) ESCROW AGENT WARRANTS ANY AND ALL SERVICES PROVIDED HEREUNDER SHALL BE PERFORMED IN A WORKMANLIKE MANNER AND IN A MANNER CONSISTENT WITH THE MEASURES ESCROW AGENT TAKES TO PROTECT ITS OWN INFORMATION OF A SIMILAR NATURE, BUT IN NO CASE LESS THAN A REASONABLE LEVEL OF CARE. EXCEPT AS SPECIFIED IN THIS SECTION, ALL CONDITIONS, REPRESENTATIONS, AND WARRANTIES INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OR CONDITIONS OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY, OR ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICE, ARE HEREBY EXCLUDED TO THE EXTENT ALLOWED BY APPLICABLE LAW. AN AGGRIEVED PARTY MUST NOTIFY ESCROW AGENT PROMPTLY UPON LEARNING OF ANY CLAIMED BREACH OF ANY WARRANTY AND, TO THE EXTENT ALLOWED BY APPLICABLE LAW, SUCH PARTY’S REMEDY FOR BREACH OF THIS WARRANTY SHALL BE SUBJECT TO THE LIMITATION OF LIABILITY AND CONSEQUENTIAL DAMAGES WAIVER IN THIS AGREEMENT. THIS DISCLAIMER AND EXCLUSION SHALL APPLY EVEN IF THE EXPRESS WARRANTY AND LIMITED REMEDY SET FORTH ABOVE FAILS OF ITS ESSENTIAL PURPOSE.

(b) Depositor warrants that all Depositor information provided hereunder is accurate and reliable.

**8. Confidential Information**

Escrow Agent shall have the obligation to implement and maintain safeguards designed to protect the confidentiality of the Deposit Material. Except as provided in this Agreement Escrow Agent shall not use, disclose, transfer or otherwise make available the Deposit Material. Escrow Agent shall not disclose the terms of this Agreement to any third party other than its financial, technical, or legal advisors, or its administrative support service providers. Any such third party shall be bound by the same confidentiality obligations as Escrow Agent. If Escrow Agent receives a subpoena or any other order from a court or other judicial tribunal pertaining to the disclosure or release of the Deposit Material, Escrow Agent

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will promptly notify the Parties to this Agreement unless prohibited by law. After notifying the Parties, Escrow Agent may comply in good faith with such order. It shall be the responsibility of Depositor or Beneficiary to challenge any such order; provided, however, that Escrow Agent does not waive its rights to present its position with respect to any such order. Escrow Agent will cooperate with the Depositor or Beneficiary, as applicable, to support efforts to quash or limit any subpoena, at such Party's expense. Any Party requesting additional assistance shall pay Escrow Agent's standard charges or as quoted upon submission of a detailed request.

**9. Limitation of Liability**

EXCEPT FOR: (I) LIABILITY FOR DEATH OR BODILY INJURY; (II) PROVEN GROSS NEGLIGENCE OR WILLFUL MISCONDUCT; OR (III) BREACH BY ESCROW AGENT OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN SECTION 8, ALL OTHER LIABILITY RELATED TO THIS AGREEMENT, IF ANY, WHETHER ARISING IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE, OF ANY PARTY TO THIS AGREEMENT SHALL BE LIMITED TO THE AMOUNT EQUAL TO ONE YEAR OF FEES PAID TO ESCROW AGENT UNDER THIS AGREEMENT. IF CLAIM OR LOSS IS MADE IN RELATION TO A SPECIFIC DEPOSIT OR DEPOSITS, SUCH LIABILITY SHALL BE LIMITED TO THE FEES RELATED SPECIFICALLY TO SUCH DEPOSITS.

**10. Consequential Damages Waiver**

EXCEPT FOR (I) A GROSSLY NEGLIGENT BREACH BY ESCROW AGENT OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN SECTION 8 OR (II) ANY ACTS OF WILLFUL MISCONDUCT, IN NO EVENT SHALL ANY PARTY TO THIS AGREEMENT BE LIABLE TO ANOTHER PARTY FOR ANY INCIDENTAL, SPECIAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, LOST PROFITS, ANY COSTS OR EXPENSES FOR THE PROCUREMENT OF SUBSTITUTE SERVICES (EXCLUDING SUBSTITUTE ESCROW SERVICES), OR ANY OTHER INDIRECT DAMAGES, WHETHER ARISING IN CONTRACT, TORT (INCLUDING NEGLIGENCE) OR OTHERWISE EVEN IF THE POSSIBILITY THEREOF MAY BE KNOWN IN ADVANCE TO ONE OR MORE PARTIES.

**11. General**

- (a) Choice of Law. The validity, interpretation, and performance of this Agreement shall be controlled by and construed under the laws of New York, as if performed wholly within the state and without giving effect to the principles of conflicts of laws.
- (b) Authorized Person(s). Depositor and Beneficiary must each authorize and designate one person whose actions will legally bind such Party ("Authorized Person" who shall be identified in the Authorized Person(s) Notices Table of this Agreement or such Party's legal representative) and who may manage the Escrow Agent escrow account through the Escrow Agent website or written instruction. The Authorized Person for each the Depositor and Beneficiary will maintain the accuracy of their name and contact information provided to Escrow Agent during the Term of this Agreement.
- (c) Right to Rely on Instructions. With respect to release of Deposit Material or the destruction of Deposit Material, Escrow Agent shall rely on instructions from a Party's Authorized Person(s); provided, that in the case of a release of the Deposit Material, such instructions are in accordance with the requirements in Exhibit C. In all other cases,



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Escrow Agent may act in reliance upon any instruction, instrument, or signature reasonably believed by Escrow Agent to be genuine and from an Authorized Person(s), officer, or other employee of a Party. Escrow Agent may assume that such representative of a Party to this Agreement who gives any written notice, request, or instruction has the authority to do so. Escrow Agent will not be required to inquire into the truth of, or evaluate the merit of, any statement or representation contained in any notice or document reasonably believed to be from such representative.

- (d) Force Majeure. No Party shall be liable for any delay or failure in performance due to events outside the defaulting Party's reasonable control, including without limitation acts of God, earthquake, labor disputes, shortages of supplies, riots, war, acts of terrorism, fire, epidemics, or delays of common carriers or other circumstances beyond its reasonable control. The obligations and rights of the excused Party shall be extended on a day-to-day basis for the time period equal to the period of the excusable delay.
- (e) Notices. All notices regarding Exhibit A (Release of Deposit Material) shall be sent by commercial express mail or other commercially appropriate means that provide prompt delivery and require proof of delivery. All other correspondence, including invoices, payments, and other documents and communications, may be sent electronically or via regular mail. The Parties shall have the right to rely on the last known address of the other Parties. Any correctly addressed notice to the last known address of the other Parties that is relied on herein, that is refused, unclaimed, or undeliverable shall be deemed effective as of the first date that said notice was refused, unclaimed, or deemed undeliverable by electronic mail, the postal authorities, or through messenger or commercial express delivery service.
- (f) No Waiver. No waiver of any right under this Agreement by any Party shall constitute a subsequent waiver of that or any other right under this Agreement.
- (g) Assignment. No assignment of this Agreement by Depositor or Beneficiary or any rights or obligations of Depositor or Beneficiary under this Agreement is permitted without the written consent of Escrow Agent, which shall not be unreasonably withheld or delayed; provided that (1) Depositor may assign this Agreement without the consent of Beneficiary or Escrow Agent in connection with a permitted assignment of all of the License Agreement, to the same person or entity successor; and (2) Beneficiary may assign this Agreement without the consent of Depositor or Escrow Agent in connection with a permitted assignment of all of the License Agreement, to the same person or entity successor. Escrow Agent shall have no obligation in performing this Agreement to recognize any successor or assign of Depositor or Beneficiary unless Escrow Agent receives clear, authoritative and conclusive written evidence of the change of Parties.
- (h) Severability. In the event any of the terms of this Agreement become or are declared to be illegal or otherwise unenforceable by any court of competent jurisdiction, such term(s) shall be null and void and shall be deemed deleted from this Agreement. All remaining terms of this Agreement shall remain in full force and effect. If this paragraph becomes applicable and, as a result, the value of this Agreement is materially impaired for any Party, as determined by such Party in its sole discretion, then the affected Party may terminate this Agreement by written notice to the other Parties.
- (i) Independent Contractor Relationship. Depositor and Beneficiary understand, acknowledge, and agree that Escrow Agent's relationship with Depositor and Beneficiary

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will be that of an independent contractor and that nothing in this Agreement is intended to or should be construed to create a partnership, joint venture, or employment relationship.

- (j) Attorneys' Fees. Any costs and fees incurred by Escrow Agent in the performance of obligations imposed upon Escrow Agent solely by virtue of its role as escrow service provider including, without limitation, compliance with subpoenas, court orders, and discovery requests shall, unless adjudged otherwise, be divided equally and paid by Depositor and Beneficiary. In any suit or proceeding between the Parties relating to this Agreement, the prevailing Party will have the right to recover from the other(s) its costs and reasonable fees and expenses of attorneys, accountants, and other professionals incurred in connection with the suit or proceeding, including costs, fees and expenses upon appeal, separately from and in addition to any other amount included in such judgment. This provision is intended to be severable from the other provisions of this Agreement, and shall survive and not be merged into any such judgment.
- (k) No Agency. No Party has the right or authority to, and shall not, assume or create any obligation of any nature whatsoever on behalf of the other Parties or bind the other Parties in any respect whatsoever.
- (l) Disputes. Any dispute, difference or question relating to or arising among (a) Escrow Agent and (b) either or both of Depositor or Beneficiary concerning the construction, meaning, effect or implementation of this Agreement or the rights or obligations of any Party hereof will be submitted to, and settled by arbitration by a single arbitrator chosen by the corresponding Regional Office of the American Arbitration Association in accordance with the Commercial Rules of the American Arbitration Association. The Depositor and Beneficiary shall both use commercially reasonable efforts to conclude the dispute resolution process within 15 business days. The Parties shall submit briefs of no more than 10 pages and the arbitration hearing shall be limited to two (2) days maximum. The arbitrator shall apply New York law. Unless otherwise agreed by the Parties, arbitration will take place in New York, New York, U.S.A. Any court having jurisdiction over the matter may enter judgment on the award of the arbitrator. Service of a petition to confirm the arbitration award may be made by regular mail or by commercial express mail, to the attorney for the Party or, if unrepresented, to the Party at the last known business address. If however, Depositor or Beneficiary refuse to submit to arbitration, the matter shall not be submitted to arbitration and Escrow Agent may submit the matter to any court of competent jurisdiction for an interpleader or similar action.
- (m) No Third Party Rights. This Agreement is made solely for the benefit of the Parties to this Agreement and their respective permitted successors and assigns, and no other person or entity shall have or acquire any right by virtue of this Agreement unless otherwise agreed to by all the Parties hereto.
- (n) Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be an original, but all of which together shall constitute one instrument.

(balance of this page left intentionally blank – signature page follows)

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**SIGNATURE PAGE to  
Three-Party Escrow Service Agreement**

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the Signing Date by their authorized representatives:

<b>DEPOSITOR:</b>		<b>BENEFICIARY:</b>	
<b>ACCESS PHARMACEUTICALS, INC.</b>		<b>AMAG PHARMACEUTICALS, INC.</b>	
<b>Signature</b>		<b>Signature</b>	
<b>Print Name</b>		<b>Print Name</b>	
<b>Title</b>		<b>Title</b>	
<b>Date</b>		<b>Date</b>	
<b>Email Address</b>		<b>Email Address</b>	

<b>ESCROW AGENT</b>	
<b>Signature</b>	
<b>Print Name</b>	
<b>Title</b>	
<b>Date</b>	
<b>Email Address</b>	

<b>Authorized Person(s) Notices Table</b>			
Please provide the name(s) and contact information of the Authorized Person(s) under this Agreement. Please complete all information as applicable. Incomplete information may result in a delay of processing.			
<b>DEPOSITOR (Required information)</b>		<b>BENEFICIARY (Required information)</b>	
Print Name		Print Name	
Title		Title	
Email Address		Email Address	
Street Address		Street Address	
Province/City/State		Province/City/State	
Postal/Zip Code		Postal/Zip Code	
Phone Number		Phone Number	
Fax Number		Fax Number	

<b>Billing Contact Information Table</b>			
Please provide the name and contact information of the Billing Contact under this Agreement. All Invoices will be sent to this individual at the address set forth below.			
<b>DEPOSITOR</b>		<b>BENEFICIARY</b>	
<input type="checkbox"/> <i>Check if same as Authorized Person</i>		<input type="checkbox"/> <i>Check if same as Authorized Person</i>	
Company Name		Company Name	
Print Name		Print Name	
Title		Title	

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Email Address		Email Address	
Street Address		Street Address	
Province/City/State		Province/City/State	
Postal/Zip Code		Postal/Zip Code	
Phone Number		Phone Number	
Fax Number		Fax Number	
Purchase Order #		Purchase Order #	

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

**Exhibit A**  
**Release of Deposit Material**

<b>Deposit Account Number</b>	
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Escrow Agent will use the following procedures to process any Beneficiary request to release Deposit Material.

**1. Release Conditions.**

Depositor and Beneficiary agree that a request for the release of the Deposit Material may only be issued by Beneficiary if such request satisfies the following condition (defined as the “**Release Condition**”):

In the form attached as Annex A-1, Beneficiary represents and warrants that a Release Event (as defined in the License Agreement) has occurred and Depositor has failed to [\*\*\*].

**2. Beneficiary’s Demand Release Work Request for Release of Deposit Material .**

Beneficiary may submit a request for release of the Deposit Material if Beneficiary believes in good faith that the Release Condition has occurred (a “**Demand Release Work Request**”). The Beneficiary’s Demand Release Work Request will be in the form attached as Annex A-1.

**3. Demand Release of Deposit Material.**

**A. [\*\*\*]**

Upon receipt of such Demand Release Work Request for (i) [\*\*\*] (ii) [\*\*\*] and (iii) [\*\*\*], Escrow Agent Escrow Agent shall provide a copy of the notice to Access, by certified mail, return receipt requested, or by commercial express mail. From the date Escrow Agent mails the notice requesting release of the Deposit Material, Depositor shall have five (5) business days to deliver to Escrow Agent Contrary Instructions. For purposes of this Agreement, “**Contrary Instructions**” shall mean the written representation by Depositor that a Release Condition has not occurred or has been cured. Upon receipt of Contrary Instructions, Escrow Agent shall send a copy to Beneficiary by certified mail, return receipt requested, or by commercial express mail. Additionally, Escrow Agent shall notify both Depositor and Beneficiary that there is a dispute to be resolved pursuant to the Dispute Resolution section of this Agreement. Escrow Agent will continue to store the Deposit Material without release pending (a) joint instructions from Depositor and Beneficiary, (b) resolution pursuant to the Dispute Resolution provisions, or (c) order of a court. If Escrow Agent does not receive Contrary Instructions from the Depositor, Escrow Agent is authorized to release the Deposit Material to the Beneficiary. Escrow Agent is entitled to receive any undisputed, unpaid Service Fees due Escrow Agent from the Parties before fulfilling the Demand Release Work Request for release of the Deposit Material covered under this Agreement. Any Party may cure a default of payment of Service Fees.

[\*\*\*] INDICATES MATERIAL THAT HAS BEEN OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED. ALL SUCH OMITTED MATERIAL HAS BEEN FILED WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 PROMULGATED UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

**B. Demand Release for [\*\*\*]**

Upon receipt of such Demand Release Work Request for a [\*\*\*], Escrow Agent shall provide a copy of the notice to Access, by certified mail, return receipt requested, or by commercial express mail. In the case of a [\*\*\*], Depositor shall not have any right or ability to deliver to Escrow Agent Contrary Instructions. Accordingly, Escrow Agent is authorized to release the Deposit Material to the Beneficiary upon receipt of such Demand Release Work Request for a [\*\*\*]. Escrow Agent is entitled to receive any undisputed, unpaid Service Fees due Escrow Agent from the Parties before fulfilling the Demand Release Work Request for release of the Deposit Material covered under this Agreement. Any Party may cure a default of payment of Service Fees.

**4. Termination of Agreement Upon Release.**

This Agreement will terminate upon the release of Deposit Material held by Escrow Agent.

**5. Rights Following Release.**

Following release of the Deposit Material, Depositor and Beneficiary shall be entitled to exercise their respective rights and obligations under the License Agreement as provided therein.

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**Annex 1 to Exhibit A (Release of Deposit Material)**

**Beneficiary Certificate**

<b>Deposit Account Number</b>	
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[Date]

Escrow Agent  
[Address]

**Re: AMAG Beneficiary Certificate – Deposit Account Number [\_\_\_\_\_]**

Dear [\_\_\_\_\_]:

Reference is hereby made to the Three Party Escrow Services Agreement (the “**Escrow Agreement**”), dated June [\_\_\_\_], 2013, by and among Access Pharmaceuticals, Inc. (“**Depositor**”), AMAG Pharmaceuticals, Inc. (“**Beneficiary**”) and [Escrow Agent] (the “**Escrow Agent**”). Except as otherwise provided below, capitalized terms used herein but not otherwise defined herein shall have the meanings assigned to them in the Escrow Agreement.

Beneficiary hereby represents and warrants that that a Release Event (as defined in the License Agreement) has occurred and Depositor has failed to deliver to Beneficiary [\*\*\*].

As such, Beneficiary hereby represents that the Release Condition has been satisfied. Accordingly, Beneficiary hereby instructs the Escrow Agent to release the Deposit Material to Beneficiary as soon as practicable in accordance with Exhibit A of the Escrow Agreement.

Sincerely,

**AMAG Pharmaceuticals, Inc.**

By: \_\_\_\_\_  
(Signature)

Name: \_\_\_\_\_

Title: \_\_\_\_\_





**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: August 14, 2013

/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, 2013

/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, 2013, 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, 2013.

/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, 2013, 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, 2013.

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