

MACROGENICS INC  
Form 10-Q  
November 12, 2014  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
**WASHINGTON, D.C. 20549**

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2014**

**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: 001-36112**

**MACROGENICS, INC.**

**(Exact name of registrant as specified in its charter)**

<b>Delaware</b> <b>(State or other jurisdiction of</b>	<b>06-1591613</b> <b>(I.R.S. Employer</b>
<b>incorporation or organization)</b>	<b>Identification No.)</b>
<b>9640 Medical Center Drive,</b>	
<b>Rockville, Maryland</b>	<b>20850</b>
<b>(Address of principal executive offices)</b>	<b>(Zip code)</b>
<b>301-251-5172</b>	
<b>(Registrant's telephone number, including area code)</b>	

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 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 definitions of "accelerated filer," "large accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer <input type="checkbox"/>	Accelerated filer <input type="checkbox"/>
Non-accelerated filer <input checked="" type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>

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

As of October 31, 2014, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 27,794,963 shares.

Table of Contents**TABLE OF CONTENTS**

	Page Number
<b>PART I.      <u>FINANCIAL INFORMATION</u></b>	
Item 1. <u>Financial Statements</u>	
<u>Consolidated Balance Sheets at September 30, 2014 (unaudited) and December 31, 2013</u>	2
<u>Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2014 and 2013 (unaudited)</u>	3
<u>Consolidated Statements of Cash Flows for the nine months ended September 30, 2014 and 2013 (unaudited)</u>	4
<u>Notes to Consolidated Financial Statements (unaudited)</u>	5
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	18
Item 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	26
Item 4. <u>Controls and Procedures</u>	26
<b>PART II.      <u>OTHER INFORMATION</u></b>	
Item 1A. <u>Risk Factors</u>	26
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	26
Item 6. <u>Exhibits</u>	27
<u>Signatures</u>	28

**Table of Contents**

**SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This report includes forward-looking statements within the meaning of federal securities laws. Forward-looking statements include statements that may relate to our plans, objectives, goals, strategies, future events, future revenues or performance, capital expenditures, financing needs and other information that is not historical information. Forward-looking statements can often be identified by the use of terminology such as subject to , believe , anticipate , plan , expect , intend , estimate , project , may , will , should , would , could , can , the negatives there and similar expressions, or by discussions of strategy.

All forward-looking statements are based upon our current expectations and various assumptions. We believe there is a reasonable basis for our expectations and beliefs, but they are inherently uncertain. We may not realize our expectations, and our beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements. The following uncertainties and factors, among others, could affect future performance and cause actual results to differ materially from those matters expressed in or implied by forward-looking statements:

our plans to develop and commercialize our product candidates;

our ongoing and planned clinical trials;

the timing of and our ability to obtain and maintain regulatory approvals for our product candidates;

our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;

our ability to identify additional products or product candidates with significant commercial potential that are consistent with our commercial objectives;

the rate and degree of market acceptance and clinical utility of our products;

our commercialization, marketing and manufacturing capabilities and strategy;

significant competition in our industry;

costs of litigation and the failure to successfully defend lawsuits and other claims against us;

economic, political and other risks associated with our international operations;

our ability to receive research funding and achieve anticipated milestones under our collaborations;

our intellectual property position;

costs of compliance and our failure to comply with new and existing governmental regulations including, but not limited to, tax regulations;

loss or retirement of key members of management;

failure to successfully execute our growth strategy, including any delays in our planned future growth; and

our failure to maintain effective internal controls.

The factors, risks and uncertainties referred to above and others are more fully described under the heading **Risk Factors** in our Annual Report on Form 10-K for the fiscal year ended December 31, 2013, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Forward-looking statements should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. The forward-looking statements contained herein represent our judgment as of the date of this report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****MACROGENICS, INC.****CONSOLIDATED BALANCE SHEETS****(in thousands, except share and per share data)**

	<b>September 30, 2014</b>	<b>December 31, 2013</b>
	<b>(unaudited)</b>	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 179,191	\$ 116,481
Accounts receivable	5,315	2,004
Prepaid expenses	2,453	972
<b>Total current assets</b>	<b>186,959</b>	<b>119,457</b>
Restricted cash	300	405
Property and equipment, net	5,633	5,035
Other assets	733	885
<b>Total assets</b>	<b>\$ 193,625</b>	<b>\$ 125,782</b>
<b>Liabilities and stockholders equity</b>		
Current liabilities:		
Accounts payable	\$ 4,388	\$ 3,169
Accrued expenses	4,031	3,584
Lease exit liability	1,589	1,439
Deferred revenue	15,617	20,267
Other liabilities	363	363
<b>Total current liabilities</b>	<b>25,988</b>	<b>28,822</b>
Lease exit liability, net of current portion	6,789	8,006
Deferred rent liability	2,708	2,904
Deferred revenue, net of current portion	19,052	7,136
<b>Total liabilities</b>	<b>54,537</b>	<b>46,868</b>
Stockholders equity:		
Common stock, \$0.01 par value 125,000,000 shares authorized, 27,772,085 and 25,177,597 shares outstanding at September 30, 2014 and December 31, 2013, respectively	278	252
Treasury stock, at cost; no shares at September 30, 2014 and 14,381 shares at December 31, 2013		(58)
Additional paid-in capital	333,838	254,453

Edgar Filing: MACROGENICS INC - Form 10-Q

Accumulated deficit	(195,028)	(175,733)
Total stockholders' equity	139,088	78,914
Total liabilities and stockholders' equity	\$ 193,625	\$ 125,782

*See accompanying notes.*

Table of Contents

## MACROGENICS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(unaudited)

(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
<b>Revenues:</b>				
Revenue from collaborative research	\$ 18,283	\$ 20,111	\$ 41,886	\$ 42,016
Grant revenue	99	121	435	1,112
Total revenues	18,382	20,232	42,321	43,128
<b>Costs and expenses:</b>				
Research and development	18,632	11,088	50,536	32,234
General and administrative	3,678	1,986	11,081	7,323
Total costs and expenses	22,310	13,074	61,617	39,557
Income (loss) from operations	(3,928)	7,158	(19,296)	3,571
Other income (expense)		(554)	1	(627)
Net comprehensive income (loss)	\$ (3,928)	\$ 6,604	\$ (19,295)	\$ 2,944
Basic net income (loss) per common share	\$ (0.14)	\$ 0.14	\$ (0.71)	\$ 0.00
Diluted net income (loss) per common share	\$ (0.14)	\$ 0.01	\$ (0.71)	\$ 0.00
Basic weighted average common shares outstanding	27,751,437	1,184,507	27,227,151	1,463,798
Diluted weighted average common shares outstanding	27,751,437	21,242,979	27,227,151	21,908,859

*See accompanying notes.*



Table of Contents

## MACROGENICS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2014	2013
<b>Cash flows from operating activities</b>		
Net income (loss)	\$ (19,295)	\$ 2,944
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation expense	1,317	835
Share-based compensation	2,249	394
Fair value adjustment of warrant liabilities		626
Changes in operating assets and liabilities:		
Accounts receivable	(3,311)	(235)
Prepaid expenses	(1,481)	(966)
Restricted cash	105	
Other assets	152	
Accounts payable	1,219	(1,941)
Accrued expenses	447	(297)
Lease exit liability	(1,067)	(466)
Deferred revenue	7,266	(13,969)
Deferred rent	(196)	87
Net cash used in operating activities	(12,595)	(12,988)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(1,914)	(2,037)
Net cash used in investing activities	(1,914)	(2,037)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock, net of offering costs	76,733	
Proceeds from stock option exercises	486	851
Net cash provided by financing activities	77,219	851
Net change in cash and cash equivalents	62,710	(14,174)
Cash and cash equivalents at beginning of period	116,481	47,743
Cash and cash equivalents at end of period	\$ 179,191	\$ 33,569

*See accompanying notes.*



**Table of Contents**

**MACROGENICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (unaudited)**

**1. Summary of Significant Accounting Policies**

*Basis of Presentation*

The accompanying unaudited interim consolidated financial statements of MacroGenics, Inc. (the Company) have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information. The financial statements include all adjustments (consisting only of normal recurring adjustments) that the management of the Company believes are necessary for a fair presentation of the periods presented. These interim financial results are not necessarily indicative of results expected for the full fiscal year or for any subsequent interim period.

The accompanying unaudited interim consolidated financial statements include the accounts of MacroGenics, Inc. and its wholly owned subsidiary, MacroGenics West, Inc. All intercompany accounts and transactions have been eliminated in consolidation. These consolidated financial statements and related notes should be read in conjunction with the financial statements and notes thereto included in the Company's 2013 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on March 20, 2014.

There have been no material changes to the significant accounting policies previously disclosed in the Company's 2013 Annual Report on Form 10-K.

*Recent Accounting Pronouncements*

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. The ASU also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. Early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative effect adjustment as of the date of adoption. Management is currently assessing what effect the adoption of ASU 2014-09 will have on the Company's consolidated financial statements and accompanying notes.

**2. Fair Value of Financial Instruments**

The fair market values of the financial instruments included in the financial statements, which include cash equivalents and money market accounts, approximate their carrying values at September 30, 2014 due to their short-term maturities. The Company accounts for recurring and non-recurring fair value measurements in accordance with FASB Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures* (ASC 820). ASC 820 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value, and requires expanded disclosures about fair value measurements. The ASC 820 hierarchy ranks the quality of reliability of inputs, or assumptions, used in the determination of fair value and requires assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 Fair value is determined by using unadjusted quoted prices that are available in active markets for identical assets and liabilities.

Level 2 Fair value is determined by using inputs other than Level 1 quoted prices that are directly or indirectly observable. Inputs can include quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets and liabilities in inactive markets. Related inputs can also include those used in valuation or other pricing models, such as interest rates and yield curves that can be corroborated by observable market data.

**Table of Contents**

Level 3 Fair value is determined by inputs that are unobservable and not corroborated by market data. Use of these inputs involves significant and subjective judgments to be made by a reporting entity e.g., determining an appropriate adjustment to a discount factor for illiquidity associated with a given security. The Company evaluates financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them each reporting period. This determination requires the Company to make subjective judgments as to the significance of inputs used in determining fair value and where such inputs lie within the ASC 820 hierarchy.

Financial assets and liabilities subject to fair value measurements were as follows (in thousands):

	<b>Fair Value Measurements at September 30, 2014</b>			
	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets Level 1</b>	<b>Significant Other Observable Inputs Level 2</b>	<b>Significant Unobservable Inputs Level 3</b>
<b>Assets:</b>				
Cash and cash equivalents	\$ 153,145	\$ 153,145	\$	\$
Money market funds	26,046	26,046		
Restricted cash	300	300		
<b>Total Assets</b>	<b>\$ 179,491</b>	<b>\$ 179,491</b>	<b>\$</b>	<b>\$</b>

	<b>Fair Value Measurements at December 31, 2013</b>			
	<b>Total</b>	<b>Quoted Prices in Active Markets for Identical Assets Level 1</b>	<b>Significant Other Observable Inputs Level 2</b>	<b>Significant Unobservable Inputs Level 3</b>
<b>Assets:</b>				
Cash and cash equivalents	\$ 90,434	\$ 90,434	\$	\$
Money market funds	26,047	26,047		
Restricted cash	405	405		
<b>Total Assets</b>	<b>\$ 116,886</b>	<b>\$ 116,886</b>	<b>\$</b>	<b>\$</b>

**3. Lease Exit Liability**

On July 16, 2008, the Company acquired Raven Biotechnologies, Inc. (Raven), a private South San Francisco-based company focused on the development of monoclonal antibody therapeutics for treating cancer. Raven was considered a development-stage enterprise as defined in ASC 915, *Development Stage Entities*.

The Company undertook restructuring activities related to the acquisition of Raven. These restructuring activities included reductions in staffing levels and the intended exit of leased facilities. All severance-related payments were

made in the year ended December 31, 2009.

In connection with these restructuring activities, as part of the cost of acquisitions, the Company established a restructuring liability attributed to an existing operating lease. The terms of the operating lease extend through 2018.

**Table of Contents**

Changes in the lease exit liability are as follows (in thousands):

Accrual balance at December 31, 2013.	\$ 9,445
Principal payments	(1,067)
Accrual balance at September 30, 2014	\$ 8,378

The purchase agreement provides for a specified total of certain contingent milestones that are based on the achievement of certain product sales derived from the acquired Raven technology. Also, a onetime payment of \$5.0 million will be made to the Raven stockholders upon the initiation of patient dosing in the first Phase 2 clinical trial of any product derived from the Raven Cancer Stem Cell Program. No payment shall be made if the Phase 2 trial start date has not occurred on or before July 15, 2018. Other consideration includes a percentage of revenue (excluding consideration for research and development and equity) received by MacroGenics for license of a product derived from the Raven Cancer Stem Cell Program and a onetime payment ranging from \$8.0 million to \$12.0 million dependent upon a specified level of sales of products derived from the Raven Cancer Stem Cell Program.

Any contingent consideration would be accounted for as additional purchase price and recorded as incremental in-process research and development expense when and if it is deemed probable that the contingencies will be attained. No additional amounts have been recorded during the three and nine months ended September 30, 2014 and 2013.

**4. Collaboration and License Agreements*****Takeda Pharmaceutical Company Limited***

In May 2014, the Company entered into a license and option agreement with Takeda Pharmaceutical Company Limited (Takeda) for the development and commercialization of MGD010, a product candidate that incorporates the Company's proprietary Dual-Affinity Re-Targeting (DART) technology to simultaneously engage CD32B and CD79B, which are two B-cell surface proteins. MGD010 is currently in pre-clinical development for the treatment of autoimmune diseases. Upon execution of the agreement, Takeda made a non-refundable payment of \$15.0 million to the Company. Takeda has an option to obtain an exclusive worldwide license for MGD010 following the completion of a pre-defined Phase 1a study. The Company will lead all product development activities until that time. If Takeda exercises its option, it will assume responsibility for future development and pay the Company a license option fee that, along with an early development milestone, will total \$18.0 million. Assuming successful development and commercialization of MGD010, the Company is eligible to receive up to an additional \$468.5 million in development, regulatory and sales milestone payments. If commercialized, the Company would receive double-digit royalties on any global net sales and has the option to co-promote MGD010 with Takeda in the United States. Finally, the Company may elect to fund a portion of Phase 3 clinical development in exchange for a North American profit share.

The Company has evaluated the license and option agreement with Takeda and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under the license and option agreement include exclusivity, research and development services through the Phase 1a study and delivery of a license for the initial research compound. The Company concluded that the MGD010 option is substantive and that the license fee payable upon exercise of the option is not a deliverable at the inception of the arrangement as there is considerable uncertainty that the option would be exercised. The Company has determined that each potential future development and regulatory milestone is substantive. Although sales milestones are not

considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. The Company's substantive performance obligations under this agreement with respect to MGD010 include an exclusivity clause to its technology as well as research and development services attributed to MGD010 through completion of a pre-defined Phase 1a study. The Company determined that these performance obligations represent a single unit of accounting, because the exclusivity clause does not have stand-alone value to Takeda without the Company's technical expertise and development through the pre-defined Phase 1a study.

After identifying the deliverables included within the arrangement, the Company determined their best estimate of selling price. The Company allocated \$10.0 million to the exclusivity clause to its technology



---

**Table of Contents**

and the research and development services and \$5.0 million to the exclusive license for the initial research compound. The Company's determination of best estimate of selling price for the research and development services relied upon other similar transactions. The Company relied upon the income approach (e.g., future cash flows) to determine the value of the license of the to-be-delivered compound along with other similar license transactions with differing indications but similar stage of development. The portion of the up-front fee allocated to the MGD010 option is being recognized over an initial 24-month period, which represents the expected period of development through the completion of a pre-defined Phase 1a study. The portion of the up-front fee allocated to the license for the initial research compound was deferred until the research collaboration and license option agreement was executed and the license delivered.

In September 2014, the Company and Takeda executed a research collaboration and license option agreement, which formalized the license for the initial research compound. Under the terms of the agreement, Takeda may identify up to three additional compounds, which will be subject to separate research and development plans. The Company determined that it could recognize the entire license fee as (1) the executed contract constituted persuasive evidence of an arrangement, (2) the delivery of the license occurred and the Company had no current or future performance obligations, (3) the total consideration for the license was fixed and known at the time of its execution and there were not any extended payment terms or rights of return, and (4) the cash was received. Therefore, the Company recognized \$5.0 million in revenue during the three months ended September 30, 2014 under this agreement. The Company is also entitled to receive reimbursements for research and development services provided to Takeda with respect to the initial research compound, subject to the execution of a separate research plan.

The Company recognized revenues of approximately \$1.3 million and \$1.7 million under the MGD010 agreement during the three and nine months ended September 30, 2014, respectively. At September 30, 2014, \$8.3 million of revenue was deferred under this agreement, \$5.0 million of which was current and \$3.3 million of which was non-current.

***Gilead Sciences, Inc.***

In January 2013, the Company entered into an agreement with Gilead Sciences, Inc. (Gilead) for Gilead to obtain exclusive worldwide rights for the research, development and commercialization of up to four DART molecules. For each molecule Gilead chooses to develop, the Company is entitled to receive a license grant fee of \$7.5 million and is further eligible to receive up to an additional \$20 to \$25 million in pre-clinical milestones and up to \$240 to \$250 million in additional clinical, regulatory and sales milestones. Upon execution of the arrangement, Gilead identified one molecule to develop for which the Company granted Gilead a license in exchange for consideration of \$7.5 million.

The Company determined that any remaining licenses are conditional deliverables, which are substantive options that were not granted with a substantial discount. The Company has determined that each potential future clinical, development and regulatory milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. Gilead also provides funding for the Company's internal and external research costs under the agreement. Additionally, Gilead would be obligated to pay the Company high single digit to low double digit royalties on product sales.

The Company has evaluated the research collaboration agreement with Gilead and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this research collaboration include a license to its technology and research and development services. The Company concluded that the deliverables do not have stand alone value and therefore, represent a

combined single unit of accounting. Due to the lack of standalone value for the license and research and development services, the combined unit of accounting (the upfront payment and the expected research and development reimbursements) is being recognized ratably over a period of 21 months, which represents the expected development period.

The Company and Gilead have also agreed to establish a joint research committee to facilitate the governance and oversight of the parties' activities under the agreements. Management considered whether participation on the joint committee may be a deliverable and determined that it was not a deliverable. Had management considered participation on the joint committee as a deliverable, it would not have had a material impact on the accounting for the arrangement.

## **Table of Contents**

The Company recognized revenues of approximately \$1.0 million and \$2.2 million under this agreement for the three months ended September 30, 2014 and 2013, respectively. The Company recognized revenues of approximately \$5.5 million and \$5.9 million under this agreement for the nine months ended September 30, 2014 and 2013, respectively. No milestones have been achieved under this agreement.

At December 31, 2013, \$3.6 million of revenue was deferred under this agreement, all of which was current. As of September 30, 2014, there was no remaining deferred revenue under this agreement.

### ***Les Laboratoires Servier***

In November 2011, the Company entered into a right-to-develop collaboration agreement with Les Laboratoires Servier and Institut de Recherches Servier (collectively, Servier) for the development and commercialization of MGA271 in all countries other than the United States, Canada, Mexico, Japan, South Korea and India.

Upon execution of the agreement, Servier made a non-refundable payment of \$20.0 million to the Company. The Company is eligible to receive up to \$30.0 million in license option fees, \$47.0 million in clinical milestone payments, \$140.0 million in regulatory milestone payments and \$208.0 million in sales milestone payments if Servier exercises the option, obtains regulatory approval for and successfully commercializes MGA271. The Company concluded that the license option fees are not deliverables at the inception of the arrangement. The Company has determined that each potential future clinical, development and regulatory milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. In the event Servier exercises its option to continue development of MGA271, Servier must pay a license option fee. Under this agreement, Servier would be obligated to pay the Company from low double digit to mid-teen royalties on product sales in its territories.

The Company has evaluated the research collaboration agreement with Servier and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company concluded that the option is substantive and that the license fee for this option is not a deliverable at the inception of the arrangement as there is considerable uncertainty that the option would be exercised and the additional fee to be paid upon exercise of the option represents its estimated selling price (i.e., no substantial discount was given). The Company's substantive performance obligations under this research collaboration include an exclusivity clause to its technology, technical, scientific and intellectual property support to the research plan and participation on an executive committee and a research and development committee. The Company determined that these performance obligations represent a single unit of accounting, since the license does not have stand-alone value to Servier without the Company's technical expertise and committee participation. As such, the initial upfront payment was deferred and was being recognized ratably over the initial 27-month period, which represented the expected period of development and the Company's participation on the research and development committee. In January 2014, the Company determined that the development period will last longer than originally estimated, and prospectively adjusted its period of recognition of the upfront payment to a 38-month period. In September 2014, the Company determined that the development period will last longer than the revised estimate, and prospectively adjusted its period of recognition of the upfront payment to a 42-month period.

During the three months ended September 30, 2014 and 2013, the Company recognized revenue of \$0.2 million and \$12.3 million (including a \$10.0 million milestone payment), respectively, under this agreement. During the nine months ended September 30, 2014 and 2013, the Company recognized revenue of \$0.6 million and \$18.9 million (including a \$10.0 million milestone payment), respectively, under this agreement.

Edgar Filing: MACROGENICS INC - Form 10-Q

At September 30, 2014 and December 31, 2013, \$0.3 million and \$0.9 million of revenue remained deferred under this agreement, respectively, all of which was current.

In September 2012, the Company entered into a second right-to-develop collaboration agreement with Servier and granted it options to obtain three separate exclusive licenses to develop and commercialize DART molecules, consisting of those designated by the Company as MGD006 and MGD007, as well as a third DART molecule, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India.

---

**Table of Contents**

Upon execution of the agreement, Servier made a non-refundable payment of \$20.0 million to the Company. In addition, the Company became eligible to receive up to \$65.0 million in license option fees, \$98.0 million in clinical milestone payments, including \$5.0 million upon Investigational New Drug (IND) acceptance for each of MGD006, MGD007 and a third DART molecule, \$300.0 million in regulatory milestone payments and \$630.0 million in sales milestone payments if Servier exercises all of the options and successfully develops, obtains regulatory approval for, and commercializes a product under each license. Through September 30, 2014, the Company has received an additional \$15.0 million in license option fees and two \$5.0 million milestone payments. In addition to these payments, the Company and Servier will share Phase 2 and Phase 3 development costs. The Company has determined that each potential future clinical, development and regulatory milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. Under this agreement, Servier would be obligated to pay the Company between high-single digit and mid-teen royalties on net product sales in its territories.

The Company has evaluated the research collaboration agreement with Servier and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company concluded that each option is substantive and that the license fees for each option are not deliverables at the inception of the arrangement and were not issued with a substantial discount. The Company's substantive performance obligations under this research collaboration include an exclusivity clause to its technology, technical, scientific and intellectual property support to the research plan and participation on an executive committee and a research and development committee. The Company determined that the performance obligations with respect to the pre-clinical development represent a single unit of accounting, since the license does not have stand-alone value to Servier without the Company's technical expertise and committee participation. As such, the initial upfront license payment was deferred and initially recognized ratably over a 29-month period, which represented the expected development period. During the third quarter of 2014, the Company and Servier further refined the research plan related to the three DARTs and as such, the development period was extended. Based on this revised development period, the Company prospectively adjusted its period of recognition of the upfront payment to a 75-month period.

During the nine months ended September 30, 2014, Servier exercised its exclusive option to develop and commercialize MGD006. As a result of the exercise, the Company received a \$15.0 million payment from Servier for its license to develop and commercialize MGD006 in its territories. Upon exercise of the option, the Company evaluated its performance obligations with respect to the license for MGD006. The Company's substantive performance obligations under this research collaboration include an exclusive license to its technology, technical, scientific and intellectual property support to the research plan and participation on an executive committee and a research and development committee. The Company determined that the performance obligations with respect to the clinical development represent a single unit of accounting, since the license does not have stand-alone value to Servier without the Company's technical expertise and committee participation. As such, the \$15.0 million license fee was deferred and is being recognized ratably over a period of 82 months, which represents the expected development period for MGD006. In accordance with the agreement, the Company and Servier will share costs incurred to develop MGD006. Reimbursement of research and development expenses received in connection with this collaborative cost-sharing agreement is recorded as a reduction to research and development expense. During the three and nine months ended September 30, 2014, the Company recorded approximately \$0.4 million and \$0.8 million as an offset to research and development costs under this collaboration arrangement, and has recorded a corresponding collaboration receivable, which is included in accounts receivable on the consolidated balance sheet.

The Company recognized revenue of \$5.8 million and \$2.2 million during the three months ended September 30, 2014 and 2013, respectively, under this agreement. The Company recognized revenue of \$15.9 million and \$6.5 million during the nine months ended September 30, 2014 and 2013, respectively, under this agreement. Revenue during the

three months ended September 30, 2014 includes the \$5.0 million payment from Servier upon the achievement of a clinical milestone related to the IND application for MGD007 clearing the 30-day review period by the U.S. Food and Drug Administration (FDA). Revenue for the nine months ended September 30, 2014 includes the MGD007 milestone payment as well as the \$5.0 million milestone payment related to the IND application for MGD006 clearing the 30-day review period by the FDA. No milestones were recognized under this agreement during the three and nine months ended September 30, 2013.

**Table of Contents**

At September 30, 2014, \$18.5 million of revenue was deferred under this agreement, \$3.3 million of which was current and \$15.2 million of which was non-current. At December 31, 2013, \$9.4 million of revenue was deferred under this agreement, \$8.6 million of which was current and \$0.8 million of which was non-current.

***Boehringer Ingelheim International GmbH***

In October 2010 the Company entered into a collaboration and license agreement with Boehringer Ingelheim International GmbH (Boehringer) to discover, develop and commercialize up to ten DART molecules which span multiple therapeutic areas. Under the terms of the agreement, the Company granted Boehringer an exclusive, worldwide, royalty-bearing license under its intellectual property to research, develop, and market DARTs generated under the agreement throughout the world.

Upon execution of the agreement, the Company received an upfront payment of \$15.0 million. The Company subsequently received three annual maintenance payments. These maintenance payments are being recognized over the estimated period of development. The Company has the potential to earn milestone payments of approximately \$41.0 million related to pre-clinical and clinical development, \$89.0 million related to regulatory milestones and \$83.0 million related to sales milestones for each of the DART programs under this agreement in the case of full commercial success of multiple DART products. The Company has determined that each potential future clinical, development and regulatory milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. Boehringer also provides funding for the Company's internal and external research costs and is required to pay the Company mid-single digit royalties on product sales.

The Company determined that the deliverables under the Boehringer agreement include the license, the research and development services to be performed by the Company, and the co-promotion/manufacturing services. The Company concluded that the co-promotional activities were optional and were subject to further negotiation upon reaching regulatory approval. As such, the co-promotional period is not included in the expected obligation period to perform services.

The Company concluded that the undelivered element of research and development services had fair value. The Company concluded that the license does not have value on a standalone basis (e.g., absent the provision of the research and development services) and therefore does not represent a separate unit of accounting. The Company concluded that because the drug candidate has not yet been developed, the license is of no value to Boehringer without the ensuing research and development activities using the DART technology, which is proprietary to the Company. Likewise, Boehringer could not sell the license to another party (without the Company agreeing to provide the research and development activities for the other party). Therefore, the upfront license fee and research and development services were treated as a combined unit of accounting and recognized over the expected obligation period associated with the research and development services through September 2015, which represents the estimated period of development.

The Company and Boehringer have also agreed to establish a joint research committee to facilitate the governance and oversight of the parties' activities under the agreements. Management considered whether participation on the joint committee may be a deliverable and determined that it was not a deliverable. However, had management considered participation on the joint committee as a deliverable, it would not have had a material impact on the accounting for the arrangement as the period of participation in this committee matched the obligation period for the research and development services.

In the third quarter of 2014, Boehringer nominated a lead candidate generated by the Company's DART technology for pre-clinical development. This formal selection of a development candidate triggered a \$2.0 million milestone payment to the Company under the agreement.

The Company recognized revenues of approximately \$4.9 million and \$2.3 million during the three months ended September 30, 2014 and 2013, respectively. The Company recognized revenues of approximately \$11.0 million and \$6.9 million during the nine months ended September 30, 2014 and 2013, respectively. Revenue during the three and nine months ended September 30, 2014 includes the \$2.0 million milestone



## **Table of Contents**

payment. At September 30, 2014, \$7.5 million of revenue was deferred under this agreement, \$7.0 million of which was current and \$0.5 million of which was non-current. At December 31, 2013, \$12.8 million of revenue was deferred under this agreement, \$7.0 million of which was current and \$5.8 million of which was non-current.

There have been no material modifications to this agreement since the adoption of ASU 2009-13, *Revenue Recognition - Multiple-Deliverable Revenue Arrangements*, on January 1, 2011.

### ***Pfizer, Inc.***

In October 2010, the Company entered into a three year agreement with Pfizer, Inc. (Pfizer) to discover, develop and commercialize up to two DART molecules. The Company granted Pfizer a non-exclusive worldwide, royalty-bearing license and received an upfront payment of \$5.0 million and has received milestone payments and funding for the Company's internal and external research costs under the agreement.

The Company is eligible to receive milestone payments of approximately \$17.0 million related to pre-clinical and clinical development and \$195.0 million related to commercialization and sales milestones for each DART program under this agreement. The Company has determined that each potential future technical and development milestone is substantive. Although sales milestones are not considered substantive, they are still recognized upon achievement of the milestone (assuming all other revenue recognition criteria have been met) because there are no undelivered elements that would preclude revenue recognition at that time. Pfizer is responsible for all pre-clinical and clinical development costs for the program. In addition, Pfizer is required to pay the Company mid-single digit to low double digit royalties on product sales. Under this collaboration, one DART program is currently being pursued and the Company completed its research obligations under this program in January 2014.

The Company has evaluated the research collaboration agreement with Pfizer and has determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under this research collaboration include an exclusive license to its technology, research and development services and manufacturing services. The Company concluded that the manufacturing services were optional and were subject to further negotiation upon reaching regulatory approval. As such, the manufacturing services are not included in the expected obligation period to perform services.

The Company determined that it had fair value of the undelivered element of the research and development services. However, the Company concluded that the license does not have value on a standalone basis (e.g., absent the provision of the research and development services) and therefore does not represent a separate unit of accounting. Facts that were considered included the development of the candidate noting that because the drug candidate has not yet been developed, the license is of no value to Pfizer without the ensuing research and development activities using the DART technology, which is proprietary to the Company. Likewise, Pfizer could not sell the license to another party (without the Company agreeing to provide the research and development activities for the other party). Therefore, the upfront license fee and research and development services were treated as a combined unit of accounting and recognized over the expected obligation period associated with the research and development services through January 2014, which represented the estimated period of development.

The \$5.0 million upfront payment received by the Company is non-refundable; therefore, there is no right of return for the license. The Company recognized revenue associated with this non-refundable upfront license fee through the expected obligation period associated with the research and development services, which ended in January 2014.

The Company and Pfizer have also agreed to establish a joint research committee to facilitate the governance and oversight of the parties' activities under the agreements. Management considered whether participation on the joint

committee may be a deliverable and determined that it was not a deliverable because it is a participating right and not an obligation of the Company. However, had management considered participation on the joint committee as a deliverable, it would not have had a material impact on the accounting for the arrangement.

The Company recognized revenues of approximately \$0.9 million during the three months ended September 30, 2013. The Company recognized revenues of approximately \$3.2 million during the nine months

## Table of Contents

ended September 30, 2013. Revenue recognized related to this agreement was de minimis during the three and nine months ended September 30, 2014. As of September 30, 2014, there was no remaining deferred revenue under this agreement.

### ***Green Cross Corporation***

In June 2010, the Company entered into a collaboration agreement with Green Cross Corp. (Green Cross) for the development of the Company's anti-HER2 antibody margetuximab. This arrangement grants Green Cross an exclusive license to conduct specified Phase 1 and Phase 2 clinical trials and commercialize margetuximab in South Korea. In March 2014, the Company and Green Cross entered into an amendment to the original agreement, causing the terms of the original agreement to be materially modified.

Upon execution of the amendment, the Company became eligible to receive reimbursement for costs incurred for Phase 2 and Phase 3 clinical trials up to \$5.5 million as well as clinical development and commercial milestone payments of up to \$2.5 million. The Company has determined that each potential clinical development and commercial milestone is substantive. The Company is also entitled to receive royalties on net sales of margetuximab in South Korea. The Company and Green Cross have formed a joint steering committee to coordinate and oversee activities on which the companies collaborate under the agreement.

The Company has evaluated the collaboration agreement with Green Cross and has determined that it is a revenue arrangement with multiple deliverables or performance obligations. As a result of the material modification to the arrangement in March 2014, the Company reassessed the entire arrangement in accordance with the guidance provided by ASC 605-25, *Multiple Element Arrangements (Revenue Recognition)* as the original agreement was accounted for prior to adopting ASU 2009-13. The Company's substantive performance obligations under this agreement include an exclusive license to its technologies, research and development services, and participation in a joint steering committee. The Company concluded that the license and the reimbursements for research and development services do not have value on a standalone basis and therefore do not represent a separate unit of accounting.

The initial \$1.0 million upfront payment received by the Company upon execution of the original agreement is non-refundable; as such, there is no right of return for the license. Therefore, the upfront license fee and participation on the joint steering committee were treated as a combined unit of accounting and will be recognized over the term of the agreement through June 2020. Further, due to the fact the research and development services are not deemed to have stand-alone value, revenue for those services should be recognized over the entire term of the agreement (through June 2020). As a result of reassessing the arrangement in accordance with ASC 605-25, the Company was required to record an adjustment on the date of the material modification to reflect the revenue that would have resulted had the entity applied the requirements of ASC 605-25 from the inception of the agreement. As a result, the Company recorded an additional \$1.3 million of revenue during the nine-month period ended September 30, 2014.

The Company recognized revenues of approximately \$112,500 and \$25,000 under this agreement during the three months ended September 30, 2014 and 2013, respectively. The Company recognized revenues of approximately \$1.6 million and \$75,000 under this agreement during the nine months ended September 30, 2014 and 2013, respectively. No milestones were achieved under this agreement during the three and nine months ended September 30, 2014 and 2013.

At September 30, 2014, there was a \$412,500 unbilled receivable balance net of deferred revenue under this agreement, which is included in other assets on the consolidated balance sheet. At December 31, 2013, \$650,000 of revenue was deferred under this agreement, \$100,000 of which was current and \$550,000 of which was non-current.

## **5. Stock-Based Compensation**

The Company's 2000 Stock Option and Incentive Plan (2000 Plan) allowed for the grant of awards in respect of an aggregate of 150,297 shares of the Company's common stock in the form of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock and restricted stock units and other performance awards. The 2000 Plan has expired, and no further awards may be issued under the plan. Any shares of common stock subject to awards under the 2000 Plan that expire, terminate, or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised, or resulting in any common stock being issued, will become available for issuance under the 2013 Stock Incentive Plan (2013 Plan) up to a specified number of shares.

**Table of Contents**

Effective February 2003, the Company implemented the 2003 Equity Incentive Plan (2003 Plan), and it was amended and approved by the Company's stockholders in 2005. The 2003 Plan allowed for the grant of awards in respect of an aggregate of 4,336,731 shares of the Company's common stock. Stock options granted under the 2003 Plan may be either incentive stock options as defined by the Internal Revenue Code (IRC), or non-qualified stock options. In October 2013, the 2003 Plan was terminated, and no further awards may be issued under the plan. Any shares of common stock subject to awards under the 2003 Plan that expire, terminate, or are otherwise surrendered, canceled, forfeited or repurchased without having been fully exercised, or resulting in any common stock being issued, will become available for issuance under the 2013 Plan, up to a specified number of shares.

In October 2013, the Company implemented the 2013 Plan. The 2013 Plan provides for the grant of stock options and other stock-based awards, as well as cash-based performance awards. The aggregate number of shares of common stock initially available for issuance pursuant to awards under the 2013 Plan was 1,960,168 shares. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each year from January 1, 2014 through and including January 1, 2023, by the lesser of (a) 1,960,168 shares, (b) 4.0% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, or (c) the number of shares of common stock determined by the Board of Directors. All of the shares available for issuance under the 2013 Plan are eligible for issuance pursuant to the exercise of incentive stock options. If an option expires or terminates for any reason without having been fully exercised, if any shares of restricted stock are forfeited, or if any award terminates, expires or is settled without all or a portion of the shares of common stock covered by the award being issued, such shares are available for the grant of additional awards. However, any shares that are withheld (or delivered) to pay withholding taxes or to pay the exercise price of an option are not available for the grant of additional awards.

The following stock-based compensation amounts were recognized for the periods indicated (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Research and development	\$ 380	\$ 113	\$ 1,062	\$ 285
General and administrative	476	24	1,187	109
Total stock-based compensation expense	\$ 856	\$ 137	\$ 2,249	\$ 394

*Employee Stock Options*

The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model using the assumptions in the following table:

	Nine Months Ended September 30,	
	2014	2013
Expected dividend yield	0%	0%
Expected volatility	67%	53%-58%
Risk-free interest rate	2.04%-2.32%	1.24%-2.05%
Expected term	6.25 years	7 years
Expected forfeiture rate	5%	5.06%



**Table of Contents**

The following table summarizes stock option activity under the Plan during the nine months ended September 30, 2014:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2013	3,200,958	\$ 4.90	6.9	
Granted	279,894	20.72		
Exercised	(307,204)	1.41		
Forfeited or expired	(44,698)	7.42		
Outstanding, September 30, 2014	3,128,950	6.62	6.7	\$ 46,144

September 30, 2014:

Exercisable	1,756,293	2.45	5.0	32,646
Vested and expected to vest	2,955,117	6.35	6.5	44,305

The weighted-average grant-date fair value of options granted for the nine months ended September 30, 2014 was \$14.75. The total intrinsic value of options exercised during the nine months ended September 30, 2014 was approximately \$8.2 million, and the total cash received for options exercised was approximately \$0.5 million. The total fair value of shares vested in the nine months ended September 30, 2014 was approximately \$2.0 million. As of September 30, 2014, the total unrecognized compensation expense related to non-vested stock options, net of related forfeiture estimates, was approximately \$9.1 million, which the Company expects to recognize over a weighted-average period of approximately four years.

**6. Commitments and Contingencies****Operating Leases**

The Company leases office and laboratory space in Rockville, Maryland, under a lease that expires on March 31, 2018, and leases a manufacturing facility in Rockville under a lease that originally expired on December 31, 2014. The Company has an option under each lease to continue the respective lease for five years under the same terms. During the nine months ended September 30, 2014, the Company extended the manufacturing facility lease until December 31, 2019. The Company also entered into a new four-year lease for additional space in the manufacturing facility effective April 1, 2014. This lease also has an option to continue the lease for five years under the same terms. The Company also subleases office and laboratory space in South San Francisco under a lease that expires on December 31, 2018. All of the leases contain rent escalation clauses. For financial reporting purposes, rent expense is charged to operations on a straight-line basis over the term of the lease.

Future minimum lease payments under noncancelable operating leases as of September 30, 2014 are as follows (in thousands):

Fourth quarter 2014	\$ 916
Year Ended December 31, 2015	3,832

Edgar Filing: MACROGENICS INC - Form 10-Q

Year Ended December 31, 2016	4,166
Year Ended December 31, 2017	4,291
Year Ended December 31, 2018	3,348
Thereafter	507
	\$ 17,060

Subsequent to September 30, 2014, the Company entered into a five year lease agreement for additional office space effective February 1, 2015. The Company also amended its office and laboratory space lease originally expiring on March 31, 2018 to be co-terminus with the new lease.



**Table of Contents*****Contingencies***

From time to time, the Company may be subject to various litigation and related matters arising in the ordinary course of business. The Company does not believe it is currently subject to any material matters where there is at least a reasonable possibility that a material loss may be incurred.

**7. Net Income (Loss) Per Share**

Basic income (loss) per common share is determined by dividing income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted income (loss) per share is computed by dividing the income (loss) attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants and the if-converted method is used to determine the dilutive effect of the Company's preferred stock.

Prior to the Company's initial public offering (IPO), net income (loss) per share was calculated under the two-class method under which all earnings (distributed and undistributed) are allocated to each class of common stock and participating securities based on their respective rights to receive dividends. In the event that the Board of Directors declared a dividend payable in cash or other property on the then-outstanding shares of common stock, the holders of the Series A-1, A-2, B, C, D, and D-2 convertible preferred stock would have been entitled to receive the amount of dividends per share of preferred stock that would be payable on the largest number of whole shares of common stock into which each share of preferred stock could then be converted. Therefore, the Series A-1, A-2, B, C, D and D-2 were participating securities. All of the outstanding shares of Series A-1, A-2, B, C, D, and D-2 convertible preferred stock converted to common stock upon the consummation of the Company's IPO.

Basic and diluted income (loss) per common share is computed as follows (in thousands except share and per share data):

	<b>Three Months Ended September 30, 2014</b>		<b>Nine Months Ended September 30, 2013</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Net income (loss)	\$ (3,928)	\$ 6,604	\$ (19,295)	\$ 2,944
Less: undistributed earnings allocated to participating securities		(6,435)		(2,944)
Net income (loss) allocable to common shares	\$ (3,928)	\$ 169	\$ (19,295)	\$
Basic weighted average common shares outstanding	27,751,437	1,184,507	27,227,151	1,463,798
Basic income (loss) per common share	\$ (0.14)	\$ 0.14	\$ (0.71)	\$ 0.00
Net income (loss)	\$ (3,928)	\$ 6,604	\$ (19,295)	\$ 2,944
Less: undistributed earnings allocated to participating securities and other add-backs to net loss		(6,404)		(2,944)
	\$ (3,928)	\$ 200	\$ (19,295)	\$

Net income (loss) allocable to common shares

Basic weighted average common shares outstanding	27,751,437	1,184,507	27,227,151	1,463,798
Effect of dilutive securities		20,058,472		20,445,061

Diluted weighted average common shares outstanding	27,751,437	21,242,979	27,227,151	21,908,859
--	------------	------------	------------	------------

Diluted income (loss) per common share \$ (0.14) \$ 0.01 \$ (0.71) \$ 0.00

In October 2013, the Company issued 5,750,000 shares of common stock in connection with its IPO and 16,955,790 shares of common stock in connection with the automatic conversion of its convertible

**Table of Contents**

preferred stock upon the closing of the IPO. In February 2014, the Company issued 2,250,000 shares of common stock in a follow-on offering. The issuance of these shares resulted in a significant increase in the Company's weighted average shares outstanding for the three and nine months ended September 30, 2014 when compared to the comparable prior year period and is expected to continue to impact the year-over-year comparability of the Company's income (loss) per share calculations for the remainder of 2014.

The following common stock equivalents were excluded from the calculation of diluted loss per share allocable to common stockholders because their inclusion would have been anti-dilutive:

	<b>Three Months Ended Sept 30,</b>		<b>Nine Months Ended Sept 30,</b>	
	<b>2014</b>	<b>2013</b>	<b>2014</b>	<b>2013</b>
Series A-1 Preferred Stock		2,156,114		2,156,114
Series A-2 Preferred Stock		392,274		392,274
Series B Preferred Stock		4,336,037		4,336,037
Series C Preferred Stock		5,909,906		5,909,906
Series D Preferred Stock		769,468		769,468
Series D-2 Preferred Stock		3,391,991		3,391,991
Warrants to purchase Series D-2 Preferred Stock		180,784		180,784
Stock Options	2,264,749	2,910,952	2,274,734	2,910,952

**Table of Contents**

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

*The following discussion of our financial condition and results of operations is based upon our unaudited consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared by us in accordance with accounting principles generally accepted in the United States of America, (GAAP), for interim periods and with Regulation S-X promulgated under the Securities Exchange Act of 1934, as amended. This discussion and analysis should be read in conjunction with these unaudited consolidated financial statements and the notes thereto as well as in conjunction with our audited consolidated financial statements and related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2013 and our subsequent Quarterly and Current Reports on Forms 10-Q and 8-K.*

**Overview**

We are a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune diseases. We generate our pipeline of product candidates from our proprietary suite of next-generation antibody technology platforms which we believe improve the performance of monoclonal antibodies and antibody-derived molecules. These product candidates, which we have identified through our understanding of disease biology and immune-mediated mechanisms, may address disease-specific challenges, which are not currently being met by existing therapies. The combination of our technology platforms and antibody engineering expertise has allowed us to generate promising product candidates and enter into several strategic collaborations with global pharmaceutical and biotechnology companies. These collaborations provide us with funding and allow us to leverage the additional expertise of our collaborators to advance the development of our product candidates.

As of September 30, 2014, we have three oncology product candidates in clinical development and we subsequently commenced a Phase 1 clinical trial on one additional product candidate. Two of these programs utilize our Fc-optimization technology and two of them are based on our Dual-Affinity Re-Targeting (DART) technology. We also intend to advance three additional pre-clinical DART product candidates to Investigational New Drug (IND) submission and commence Phase 1 clinical trials with these product candidates in 2015. Key ongoing programs include:

*Margetuximab* is an Fc-optimized monoclonal antibody that targets HER2-expressing tumors, including breast, gastroesophageal and other cancers. HER2, or human epidermal growth factor receptor 2, is critical for the growth of many types of tumors. We are currently enrolling a Phase 2a clinical trial in metastatic breast cancer and are planning a Phase 3 clinical trial in metastatic breast cancer which will commence in the third quarter of 2015. We no longer plan to initiate a Phase 3 study in advanced gastroesophageal cancer.

*MGA271* is an Fc-optimized monoclonal antibody that targets B7-H3, a member of the B7 family of molecules and is over-expressed on a wide variety of solid tumor types. We expect to complete the first three dose expansion cohorts of a Phase 1 clinical trial by the end of 2014. We plan to initiate additional expansion cohorts using MGA271 as monotherapy in other tumor types in the fourth quarter of 2014, as well as combining MGA271 with other therapies for certain tumor types beginning in 2015.

*MGD006* is a humanized DART molecule that recognizes both CD123, the interleukin-3 receptor (IL3R) alpha chain which is expressed on leukemia and leukemic stem cells, but at very low levels if at all on normal hematopoietic stem cells, and CD3, which is expressed on T cells. We initiated our Phase 1 clinical trial with this program in the second quarter of 2014.

*MGD007* is a humanized DART molecule that recognizes both the glycoprotein gpA33, expressed on gastrointestinal tumors, including more than 95% of human colon cancers, and CD3, which is expressed on T cells. In July 2014, the IND application for *MGD007* was cleared by the FDA. We commenced a Phase 1 clinical trial with this molecule subsequent to September 30, 2014.

*MGD010* is a humanized DART molecule that targets both CD32B, a co-inhibitory molecule, and CD79B, part of the B cell antigen receptor complex, two proteins expressed on the immune system's B cells.

---

**Table of Contents**

*MGD011* is a humanized DART molecule that recognizes both CD19, found on the surface of B-cells, and CD3, which is expressed on T cells.

We commenced active operations in 2000, and have since devoted substantially all of our resources to staffing our company, business planning, raising capital, developing our technology platforms, identifying potential product candidates, undertaking pre-clinical studies and conducting clinical trials. We have not generated any revenues from the sale of any products to date. We have financed our operations primarily through the private placements of convertible preferred stock, the public offerings of our common stock, collaborations, and government grants and contracts. From inception through September 30, 2014, we received \$151.3 million from the sale of convertible preferred stock and warrants. We raised \$85.6 million (\$83.8 million net of expenses and deferred financing costs) in October 2013 through the sale of common stock in connection with our Initial Public Offering (IPO) and exercise by the underwriters of their over-allotment option. We raised an additional \$77.2 million (\$76.7 million net of expenses and deferred financing costs) through a follow-on public offering of our common stock and full exercise by the underwriters of their over-allotment option in February 2014. In addition, we have received significant non-equity capital from our collaborators in the form of upfront fees, milestone payments, annual maintenance payments and license option fees as well as reimbursement payments through our collaborations and government grants and contracts. Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our cash and cash equivalents as of September 30, 2014, combined with the collaboration payments we anticipate receiving, will enable us to fund the clinical development of margetuximab, MGA271, MGD006, MGD007, MGD010, MGD011, and an additional pre-clinical DART oncology product candidate into 2017, assuming all of our collaboration programs advance as currently contemplated.

Through September 30, 2014, we had an accumulated deficit of \$195.0 million. We expect that over the next several years we will increase our expenditures in research and development in connection with our ongoing activities with several clinical trials.

**Strategic Collaborations and Licenses**

We have entered into several strategic collaborations which provide us with significant additional funding in order to continue development of our pipeline and to extend our technology platforms and on-going programs. Our collaborations have allowed us to speed up the progress of our on-going pre-clinical and clinical stage programs. Our most significant strategic collaborations include the following:

*Takeda.* In May 2014, we entered into a license and option agreement with Takeda for the development and commercialization of MGD010, a product candidate that incorporates our proprietary DART technology to simultaneously engage CD32B and CD79B, which are two B-cell surface proteins. MGD010 is currently in pre-clinical development for the treatment of autoimmune diseases. Upon execution of the agreement, Takeda made a non-refundable payment of \$15.0 million to us. Takeda has an option to obtain an exclusive worldwide license for MGD010 following the completion of a pre-defined Phase 1a study. We will lead all product development activities until that time. If Takeda exercises its option, it will assume responsibility for future development and pay us a license option fee that, when combined with an early development milestone, would total \$18.0 million. Assuming successful development and commercialization of MGD010, we are eligible to receive up to an additional \$468.5 million in development, regulatory and sales milestone payments. If commercialized, we would receive double-digit royalties on any global net sales and have the option to co-promote MGD010 with Takeda in the United States. Finally, we may elect to fund a portion of Phase 3 clinical development in exchange for a North American profit share.

In September 2014, we entered into a research collaboration and license option agreement with Takeda for an initial research compound and up to three additional compounds. Under the terms of this agreement, Takeda received an option to obtain an exclusive worldwide license for each of four product candidates and will fund all research and development activities related to the programs, including reimbursement of our expenses. Assuming successful development and commercialization by Takeda, we could receive up to approximately \$400 million in program initiation, pre-clinical, clinical, regulatory and commercialization milestone payments for each of the four potential product candidates. If commercialized, we would receive double-digit royalties on any global net sales and have the option to co-promote each product candidate with Takeda in the United States. Finally, we may elect to fund a portion of Phase 3 clinical development of each product candidate in exchange for a North American profit share.

---

**Table of Contents**

*Servier.* In November 2011, we entered into a collaboration agreement with Servier under which we granted Servier an option to obtain an exclusive license to develop and commercialize MGA271 in all countries other than the United States, Canada, Mexico, Japan, South Korea and India. We received a \$20.0 million option grant fee and a \$10.0 million milestone payment, and may be eligible to receive up to approximately \$415.0 million in license fees and clinical, development, regulatory and sales milestone payments. In the event Servier exercises its option, Servier must pay a license option fee, which we estimate to be \$30.0 million, based on the number of different indications represented within the planned Phase 1 patient population. We and Servier will share Phase 2 and Phase 3 development costs.

In September 2012, we entered into a second agreement with Servier and granted it options to obtain three separate exclusive licenses to develop and commercialize DART molecules, consisting of those designated by us as MGD006 and MGD007, as well as a third DART molecule, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India. We received a \$20.0 million upfront option fee. In addition, we became eligible to receive up to approximately \$1.0 billion in additional license fees, and clinical, development, regulatory and sales milestone payments if Servier exercises all three of its options and successfully develops, obtains regulatory approval for, and commercializes a product under each license, including \$5.0 million upon IND acceptance for each of MGD006, MGD007 and a third DART molecule. In addition to these milestone payments, we and Servier will share Phase 2 and Phase 3 development costs.

In February 2014, Servier exercised its option to develop and commercialize MGD006, for which we received a \$15.0 million license option fee. We also received a \$5.0 million milestone payment from Servier in connection with the IND application for MGD006 clearing the 30-day review period by the U.S. Food and Drug Administration (FDA). In July 2014, the IND application for MGD007 cleared the 30-day review period by the FDA, which triggered an additional \$5.0 million milestone payment from Servier.

Additionally, under both agreements, Servier would be obligated to pay us low- to mid-double digit royalties on product sales in its territories.

*Boehringer.* In October 2010, we entered into an agreement with Boehringer to discover, develop and commercialize up to ten DART molecules which may span multiple therapeutic areas. We granted Boehringer an exclusive worldwide, royalty-bearing license and received an upfront payment of \$15.0 million. In the third quarter of 2014, Boehringer nominated a lead candidate generated by our DART technology for pre-clinical development. This formal selection of a development candidate triggered a \$2.0 million milestone payment to us under the agreement. We have the potential to earn development, regulatory and sales milestone payments that can reach up to approximately \$210.0 million for each of the DART programs under this agreement. Boehringer provides funding for our internal and external research costs and is required to pay us mid-single digit royalties on product sales.

**Critical Accounting Policies and Significant Judgments and Estimates**

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our consolidated financial statements. A summary of our critical accounting policies is presented in Part II, Item 7, of our Annual Report on Form 10-K for the year ended December 31, 2013. There have been no material changes to our critical accounting policies during the nine months ended September 30, 2014.

*Recent Accounting Pronouncements*



In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2014-09, *Revenue from Contracts with Customers* (ASU 2014-09). ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies

**Table of Contents**

recognize revenue based on the value of transferred goods or services as they occur in the contract. The ASU also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for annual reporting periods beginning after December 15, 2016. Early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative effect adjustment as of the date of adoption. Management is currently assessing what effect the adoption of ASU 2014-09 will have on our consolidated financial statements and accompanying notes.

**Table of Contents****Results of Operations*****Research and Development Revenue***

The following represents a comparison of our research and development revenue for the three and nine months ended September 30, 2014 and 2013:

	<b>Three Months Ended September 30, Increase/(Decrease)</b>			
	<b>2014</b>	<b>2013</b>		
	<b>(dollars in millions)</b>			
Revenue from collaborative research	\$ 18.3	\$ 20.1	\$ (1.8)	(9%)
Grant revenue	0.1	0.1		0%
<b>Total revenue</b>	<b>\$ 18.4</b>	<b>\$ 20.2</b>	<b>\$ (1.8)</b>	<b>(9%)</b>

	<b>Nine Months Ended September 30, Increase/(Decrease)</b>			
	<b>2014</b>	<b>2013</b>		
	<b>(dollars in millions)</b>			
Revenue from collaborative research	\$ 41.9	\$ 42.0	\$ (0.1)	(0%)
Grant revenue	0.4	1.1	(0.7)	(61%)
<b>Total revenue</b>	<b>\$ 42.3</b>	<b>\$ 43.1</b>	<b>\$ (0.8)</b>	<b>(2%)</b>

The decrease in collaboration revenue of \$1.8 million for the three months ended September 30, 2014 compared to the same period in 2013 is primarily due to a decrease in revenue recognition related to the Servier MGA271 agreement as the estimated development period, and therefore the revenue recognition period of previously deferred revenues, was extended. Additionally, we received less reimbursement under the Gilead agreement, and we recognized revenue under the Pfizer agreement in 2013, but the development period, and therefore the related revenue recognition period, was completed in January 2014. These decreases were partially offset by increases in revenue under the Boehringer, Servier and Takeda agreements. The decrease in collaboration revenue of \$0.1 million for the nine months ended September 30, 2014 compared to the same period in 2013 is due to a decrease in revenue recognition related to the Servier MGA271 agreement and the decrease in revenue under the Pfizer agreement. These decreases were partially offset by the receipt of two \$5.0 million milestone payments under our agreement with Servier, revenue recognized related to the Green Cross amendment and resulting accounting adjustment of \$1.3 million (see Note 4 to the financial statements for additional information), increased revenue under the Boehringer agreement, including the \$2.0 million milestone received in the third quarter of 2014, and revenue recognized under the Takeda agreement.

Grant revenue decreased in the three and nine month periods ended September 30, 2014 as compared to the same periods in 2013 due primarily to less activity on the Dengue virus grant.

**Table of Contents****Research and Development Expense**

The following represents a comparison of our research and development expense for the three and nine months ended September 30, 2014 and 2013:

	<b>Three Months Ended September 30, Increase/(Decrease)</b>			
	<b>2014</b>	<b>2013</b>	<b>(dollars in millions)</b>	
Margetuximab	\$ 6.3	\$ 1.3	\$ 5.0	385%
MGA271	3.5	1.2	2.3	192%
MGD006	0.6	2.1	(1.5)	(71%)
MGD007	0.9	0.9		0%
MGD010	1.2	1.1	0.1	9%
MGD011	1.1	1.1		0%
Other pre-clinical and clinical programs, collectively	5.0	3.4	1.6	47%
Total research and development expense	\$ 18.6	\$ 11.1	\$ 7.5	68%

	<b>Nine Months Ended September 30, Increase/(Decrease)</b>			
	<b>2014</b>	<b>2013</b>	<b>(dollars in millions)</b>	
Margetuximab	\$ 13.9	\$ 4.4	\$ 9.5	216%
MGA271	11.4	4.8	6.6	138%
MGD006	2.8	6.9	(4.1)	(59%)
MGD007	3.1	2.2	0.9	41%
MGD010	2.5	1.8	0.7	39%
MGD011	3.6	2.3	1.3	57%
Other pre-clinical and clinical programs, collectively	13.2	9.8	3.4	35%
Total research and development expense	\$ 50.5	\$ 32.2	\$ 18.3	57%

During the three and nine months ended September 30, 2014, our research and development expense increased by \$7.5 million and \$18.3 million, respectively, compared to the same periods in 2013. This increase was due primarily to the initiation of clinical manufacturing activities for two product candidates, preparations for the margetuximab Phase 3 study, expansion of the MGA271 Phase 1 study and preparations for the MGD006 and MGD007 Phase 1 studies.

**General and Administrative Expense**

The following represents a comparison of our general and administrative expense for the three and nine months ended September 30, 2014 and 2013:

	<b>Three Months Ended September 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2014</b>	<b>2013</b>		
	<b>(dollars in millions)</b>			
General and administrative expense	\$ 3.7	\$ 2.0	\$ 1.7	85%

	<b>Nine Months Ended September 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2014</b>	<b>2013</b>		
	<b>(dollars in millions)</b>			
General and administrative expense	\$ 11.1	\$ 7.3	\$ 3.8	51%

General and administrative expense increased for the three and nine months ended September 30, 2014 by \$1.7 million and \$3.8 million, respectively, compared to the same periods in 2013 primarily due to an increase in stock-based compensation expense and increased insurance, professional fees and other costs associated with public company operations in 2014.

**Table of Contents*****Other Income (Expense)***

Other expense for the three and nine months ended September 30, 2013 is primarily due to the change in the fair market value of the preferred stock warrant liability. This liability was settled in connection with our IPO in October 2013 and as such, there were no similar charges in the nine months ended September 30, 2014.

***Cash Flows***

The following table represents a summary of our cash flows for the nine months ended September 30, 2014 and 2013:

	<b>Nine Months Ended September 30,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(dollars in millions)</b>	
<b>Net cash provided by (used in):</b>		
Operating activities	\$ (12.6)	\$ (13.0)
Investing activities	(1.9)	(2.0)
Financing activities	77.2	0.9
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>\$ 62.7</b>	<b>\$ (14.2)</b>

***Operating Activities***

Net cash used in operating activities reflects, among other things, amounts used to fund our clinical trials and pre-clinical activities, including toxicology studies. The difference between net cash used in operating activities during the nine months ended September 30, 2014 and the same period in 2013 was primarily due to receipt of \$25.0 million from Servier and \$15.0 million from Takeda in 2014, offset by increased spending on contract manufacturing activities and clinical trials.

***Investing Activities***

Net cash used in investing activities was primarily due to the acquisition of additional lab equipment needed to further our research and development activities.

***Financing Activities***

Net cash provided by financing activities for the nine months ended September 30, 2014 includes approximately \$77.0 million of net proceeds from our February 2014 follow-on equity offering and cash from stock option exercises. Net cash provided by financing activities for the nine months ended September 30, 2013 includes cash from stock option exercises.

**Liquidity and Capital Resources**

We have financed our operations primarily through the private placements of convertible preferred stock, the public offerings of our common stock, upfront fees, milestone payments, annual maintenance payments and license option fees from collaborators and reimbursement through government grants and contracts. As of September 30, 2014, we

had \$179.2 million in cash and cash equivalents.

In addition to our existing cash and cash equivalents, we expect to continue to receive additional reimbursement from our collaborators for research and development services rendered, additional milestone and opt-in payments and grant revenue. However, our ability to receive these milestone payments is dependent upon our ability to successfully complete specified research and development activities and is therefore uncertain at this time.

**Table of Contents**

***Funding Requirements***

We have not generated any revenue from product sales to date and do not expect to do so until such time as we obtain regulatory approval of and commercialize one or more of our product candidates. As we are currently in the clinical trial stage of development, it will be some time before we expect to achieve this and it is uncertain that we ever will. We expect that we will continue to increase our operating expenses in connection with ongoing as well as additional clinical trials and pre-clinical development of product candidates in our pipeline. We expect to continue our collaboration arrangements and will look for additional collaboration opportunities. We also expect to continue our efforts to pursue additional grants and contracts from the U.S. government in order to further our research and development. Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our existing cash and cash equivalents as of September 30, 2014, combined with the collaboration payments we anticipate receiving, will enable us to fund the clinical development of margetuximab, MGA271, MGD006, MGD007, MGD010, MGD011 and an additional pre-clinical DART oncology product candidate into 2017, assuming all of our programs advance as currently contemplated.

**Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, as defined under the rules and regulations of the Securities and Exchange Commission.



## **Table of Contents**

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

Our primary objective when considering our investment activities is to preserve capital in order to fund our operations. Our primary exposure to market risk is related to changes in interest rates. Our current investment policy is to invest principally in deposits and securities issued by the U.S. government and its agencies, Government Sponsored Enterprise agency debt obligations, corporate debt obligations and money market instruments. As of September 30, 2014, we had cash and cash equivalents of \$179.2 million, of which \$26.0 million was invested in money market funds and the remainder was in our corporate operating account. We do not believe that our cash and cash equivalents have significant risk.

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

#### **Disclosure Controls and Procedures**

Our management, including our principal executive and principal financial officers, has evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2014. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in this Quarterly Report on Form 10-Q has been appropriately recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosure. Based on that evaluation, our principal executive and principal financial officers have concluded that our disclosure controls and procedures are effective at the reasonable assurance level.

#### **Changes in Internal Control**

No change in our internal control over financial reporting has occurred during the quarterly period ended September 30, 2014, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II. OTHER INFORMATION**

### **Item 1A. Risk Factors**

For information regarding factors that could affect our results of operations, financial condition and liquidity, see the risk factors discussion provided under "Risk Factors" in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See also, "Special Note Regarding Forward-Looking Statements" included in this Quarterly Report on Form 10-Q.

### **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

#### ***Use of Proceeds from Registered Securities***

In October 2013, we issued and sold 5,750,000 shares of our common stock, including 750,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares, in our initial public offering at a public offering price of \$16.00 per share, for aggregate gross proceeds of \$92.0 million. All of the shares

Edgar Filing: MACROGENICS INC - Form 10-Q

issued and sold in our initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-190994), which was declared effective by the SEC on October 9, 2013.

There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on October 11, 2013, and we continue to use the proceeds in the manner described in such final prospectus and in our Annual Report on Form 10-K for the year ended December 31, 2013.

**Table of Contents**

**Item 6. Exhibits**

31.1	Rule 13a-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) Certification of Principal Financial Officer
32.1	Section 1350 Certification of Principal Executive Officer
32.2	Section 1350 Certification of Principal Financial Officer
101.INS	XBRL Instance Document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Labels Linkbase Document
101.PRE	XBRL Presentation Linkbase Document

Table of Contents

**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.

MACROGENICS, INC.

BY: /s/ Scott Koenig  
Scott Koenig, M.D., Ph.D.  
President and Chief Executive Officer  
(Principal Executive Officer)

BY: /s/ James Karrels  
James Karrels  
Vice President and Chief Financial Officer  
(Principal Financial Officer)

Dated: November 12, 2014

**Table of Contents**

EXHIBIT INDEX

Exhibit Page Number

31.1	Rule 13a-14(a) Certification of Principal Executive Officer
31.2	Rule 13a-14(a) Certification of Principal Financial Officer
32.1	Section 1350 Certification of Principal Executive Officer
32.2	Section 1350 Certification of Principal Financial Officer
101.INS	XBRL Instance Document
101.SCH	XBRL Schema Document
101.CAL	XBRL Calculation Linkbase Document
101.DEF	XBRL Definition Linkbase Document
101.LAB	XBRL Labels Linkbase Document
101.PRE	XBRL Presentation Linkbase Document