

MACROGENICS INC
Form 10-Q
November 02, 2016

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

FORM 10-Q

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

For the quarterly period ended September 30, 2016

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)

Delaware 06-1591613
(State or other jurisdiction of (I.R.S. Employer
incorporation or organization) Identification No.)

9704 Medical Center Drive 20850
Rockville, Maryland
(Address of principal executive offices) (Zip code)

301-251-5172
(Registrant's telephone number, including area code)

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):

Edgar Filing: MACROGENICS INC - Form 10-Q

Large accelerated filer

Accelerated filer

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

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

As of October 31, 2016, the number of outstanding shares of the registrant's common stock, par value \$0.01 per share, was 34,835,724 shares.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Consolidated Balance Sheets at September 30, 2016 (unaudited) and December 31, 2015

Consolidated Statements of Operations and Comprehensive Income (Loss) for the three and nine months ended September 30, 2016 and September 30, 2015 (unaudited)

Consolidated Statements of Cash Flows for the nine months ended September 30, 2016 and September 30, 2015 (unaudited)

Notes to Consolidated Financial Statements (unaudited)

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Item 4. Controls and Procedures

PART II. OTHER INFORMATION

Item 1A. Risk Factors

Item 6. Exhibits

Signatures

FORWARD-LOOKING STATEMENTS

This report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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. Many of these statements appear, in particular, under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations".

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 thereof, variations thereon 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 enter into new collaborations or to identify additional products or product candidates with significant commercial potential that are consistent with our strategic 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 ability to protect and enforce patents and other intellectual property;
- costs of compliance and our potential failure to comply with new and existing governmental regulations including, but not limited to, tax regulations;
- loss or retirement of key members of management; and
- failure to successfully execute our growth strategy, including any delays in our planned future growth.

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, 2015. 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 do not undertake and specifically decline any obligation to update, republish or revise forward-looking statements to reflect future events or circumstances or to reflect the occurrences of unanticipated events except as required by law.

PART I. FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

MACROGENICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

| | September 30, 2016 | December 31, 2015 |
|--|-----------------------|----------------------|
| | (unaudited) | |
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 109,901 | \$ 196,172 |
| Marketable securities | 201,222 | 142,877 |
| Accounts receivable | 3,008 | 1,224 |
| Prepaid expenses | 1,311 | 1,806 |
| Other current assets | 844 | 305 |
| Total current assets | 316,286 | 342,384 |
| Property and equipment, net | 18,473 | 14,841 |
| Marketable securities, non-current | 3,001 | – |
| Other assets | 2,104 | 2,044 |
| Total assets | \$ 339,864 | \$ 359,269 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable | \$ 1,374 | \$ 2,967 |
| Accrued expenses | 15,370 | 11,708 |
| Deferred revenue | 3,783 | 5,866 |
| Lease exit liability | 1,525 | 2,020 |
| Other liabilities | – | 727 |
| Total current liabilities | 22,052 | 23,288 |
| Deferred revenue, net of current portion | 9,794 | 12,631 |
| Lease exit liability, net of current portion | 715 | 2,693 |
| Deferred rent liability | 6,474 | 7,320 |
| Other liabilities | 727 | – |
| Total liabilities | 39,762 | 45,932 |
| Stockholders' equity: | | |
| Common stock, \$0.01 par value – 125,000,000 shares authorized, 34,813,334 and 34,345,754 shares outstanding at September 30, 2016 and December 31, 2015, respectively | 348 | 343 |
| Additional paid-in capital | 557,667 | 547,185 |
| Accumulated deficit | (257,931) | (234,186) |
| Accumulated other comprehensive income (loss) | 18 | (5) |
| Total stockholders' equity | 300,102 | 313,337 |
| Total liabilities and stockholders' equity | \$ 339,864 | \$ 359,269 |

See accompanying notes.

Edgar Filing: MACROGENICS INC - Form 10-Q

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, | |
|--|-------------------------------------|-------------|------------------------------------|------------|
| | 2016 | 2015 | 2016 | 2015 |
| Revenues: | | | | |
| Revenue from collaborative agreements | \$2,014 | \$14,681 | \$82,404 | \$91,444 |
| Revenue from government agreements | 1,241 | — | 4,370 | 1,232 |
| Total revenues | 3,255 | 14,681 | 86,774 | 92,676 |
| Costs and expenses: | | | | |
| Research and development | 30,296 | 24,103 | 90,982 | 68,227 |
| General and administrative | 7,224 | 6,021 | 20,596 | 16,050 |
| Total costs and expenses | 37,520 | 30,124 | 111,578 | 84,277 |
| Income (loss) from operations | (34,265) | (15,443) | (24,804) | 8,399) |
| Other income (expense) | 419 | 1 | 1,059 | (88) |
| Net income (loss) | (33,846) | (15,442) | (23,745) | 8,311) |
| Other comprehensive income (loss): | | | | |
| Unrealized gain (loss) on investments | (41) | - | 23 | - |
| Comprehensive income (loss) | \$(33,887) | \$(15,442) | \$(23,722) | \$8,311) |
| | | | | |
| Basic net income (loss) per common share | \$(0.97) | \$(0.46) | \$(0.69) | \$0.27 |
| Diluted net income (loss) per common share | \$(0.97) | \$(0.46) | \$(0.69) | \$0.25 |
| Basic weighted average common shares outstanding | 34,766,440 | 33,339,163 | 34,629,330 | 30,952,458 |
| Diluted weighted average common shares outstanding | 34,766,440 | 33,339,163 | 34,629,330 | 32,960,233 |

See accompanying notes.

MACROGENICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

| | Nine Months Ended September 30, | |
|--|------------------------------------|---------|
| | 2016 | 2015 |
| Cash flows from operating activities | | |
| Net income (loss) | \$(23,745) | \$8,311 |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | |
| Depreciation and amortization expense | 5,634 | 1,671 |
| Share-based compensation | 9,126 | 5,631 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,784) | 191 |
| Prepaid expenses | 495 | 2,227 |
| Other assets | (599) | 300 |
| Accounts payable | (133) | 872 |
| Accrued expenses | 3,895 | 1,190 |

Edgar Filing: MACROGENICS INC - Form 10-Q

| | | |
|---|------------|------------|
| Lease exit liability | (2,473) | (2,833) |
| Deferred revenue | (4,920) | (11,668) |
| Deferred rent | (846) | 4,602 |
| Net cash provided by (used in) operating activities | (15,350) | 10,494 |
| Cash flows from investing activities | | |
| Purchases of marketable securities | (269,697) | – |
| Proceeds from sale and maturities of marketable securities | 207,733 | – |
| Purchases of property and equipment | (10,319) | (6,417) |
| Net cash used in investing activities | (72,283) | (6,417) |
| Cash flows from financing activities | | |
| Proceeds from issuance of common stock, net of offering costs | – | 203,467 |
| Proceeds from stock option exercises | 1,362 | 632 |
| Net cash provided by financing activities | 1,362 | 204,099 |
| Net change in cash and cash equivalents | (86,271) | 208,176 |
| Cash and cash equivalents at beginning of period | 196,172 | 157,591 |
| Cash and cash equivalents at end of period | \$ 109,901 | \$ 365,767 |

See accompanying notes.

MACROGENICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

1. Basis of Presentation and Recently Issued Accounting Standards

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 UK Limited. 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 2015 Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 29, 2016.

There have been no material changes to the significant accounting policies previously disclosed in the Company's 2015 Annual Report on Form 10-K other than the adoption of ASU No. 2015-17, Income Taxes, Balance Sheet Classification of Deferred Taxes, as disclosed in the Recently Issued Accounting Standards section below. The new guidance requires all deferred tax assets and liabilities to be classified as noncurrent on the balance sheet.

Recently Issued Accounting Standards

In November 2015, the Financial Accounting Standards Board (FASB) issued ASU No. 2015-17, Income Taxes, Balance Sheet Classification of Deferred Taxes (ASU 2015-17). ASU 2015-17 requires entities to present deferred tax assets and deferred tax liabilities as noncurrent on a classified balance sheet. ASU 2015-17 is effective for annual and interim reporting periods after December 15, 2016 and companies are permitted to apply ASU 2015-17 either prospectively or retrospectively. Early adoption of ASU 2015-17 is permitted. The Company adopted ASU 2015-17 on a prospective basis in the first quarter of 2016. The prior reporting period was not retrospectively adjusted. The adoption of this guidance had no impact on the Company's results of operations or cash flows.

In May 2014, FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09) as modified by ASU No. 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date (ASU 2014-14). 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, 2017, and interim periods therein. Early adoption at the original effective date, for interim and annual reporting periods beginning after December 15, 2016, will be permitted. The new standard may be adopted either retrospectively or on a modified retrospective basis whereby the new standard would be applied to new contracts and existing contracts with remaining performance obligations as of the effective date, with a cumulative catch-up adjustment recorded to beginning retained earnings at the effective date for existing contracts with remaining performance obligations. Management is currently assessing which adoption method will be selected and what effect the adoption of ASU 2014-09 will have on the Company's consolidated financial statements and accompanying notes.

In February 2016, FASB issued ASU No. 2016-02, Leases (ASU 2016-02) that provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. ASU 2016-02 requires a lessee to recognize assets and liabilities on the balance sheet for operating leases and changes many key definitions, including the definition of a lease. ASU 2016-02 includes a short-term lease exception for leases with a term of 12 months or less, in which a lessee can make an accounting policy election not to recognize lease assets and lease liabilities. Lessees will continue to differentiate between finance leases (previously referred to as capital leases) and operating leases, using classification criteria that are substantially similar to the previous guidance. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with earlier application permitted. The Company is currently evaluating the effect of the standard on its consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting (ASU 2016-09). This amendment addresses several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within that year. Early adoption is permitted. The Company is evaluating the impact of the standard on its consolidated financial statements and related disclosures.

2. Fair Value of Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and accrued expenses. The carrying amount of accounts receivable, accounts payable and accrued expenses are generally considered to be representative of their respective fair values because of their short-term nature. 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.

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 measured at fair value on a recurring basis were as follows (in thousands):

Fair Value Measurements at September 30, 2016

Edgar Filing: MACROGENICS INC - Form 10-Q

| | Total | Quoted Prices in Active Markets for Identical Assets Level 1 | Significant Other Observable Inputs Level 2 | Significant Unobservable Inputs Level 3 |
|--|-----------|---|---|--|
| Assets: | | | | |
| Money market funds | \$46,991 | \$46,991 | \$– | \$ – |
| Government-sponsored enterprises | 37,655 | – | 37,655 | – |
| Corporate debt securities | 166,568 | – | 166,568 | – |
| Total assets measured at fair value ^(a) | \$251,214 | \$46,991 | \$204,223 | \$ – |

(a) Total assets measured at fair value at September 30, 2016, includes approximately \$47.0 million reported in cash and cash equivalents on the balance sheet.

Fair Value Measurements at December 31, 2015

| | Total | Quoted Prices in Active Markets for Identical Assets Level 1 | Significant Other Observable Inputs Level 2 | Significant Unobservable Inputs Level 3 |
|--|-----------|---|---|--|
| Assets: | | | | |
| Money market funds | \$62,353 | \$62,353 | \$– | \$ – |
| U.S. Treasury securities | 9,349 | – | 9,349 | – |
| Government-sponsored enterprises | 41,202 | – | 41,202 | – |
| Corporate debt securities | 137,928 | – | 137,928 | – |
| Total assets measured at fair value ^(a) | \$250,832 | \$62,353 | \$188,479 | \$ – |

(a) Total assets measured at fair value at December 31, 2015, includes approximately \$108.0 million reported in cash and cash equivalents on the balance sheet.

The fair value of Level 2 securities is determined from market pricing and other observable market inputs for similar securities obtained from various third-party data providers. These inputs either represent quoted prices for similar assets in active markets or have been derived from observable market data.

3. Marketable Securities

Available-for-sale marketable securities as of September 30, 2016 and December 31, 2015 were as follows (in thousands):

| September 30, 2016 | | | |
|--------------------|-------|-------|------|
| Amortized | Gross | Gross | Fair |

Edgar Filing: MACROGENICS INC - Form 10-Q

| | Cost | Unrealized Gains | Unrealized Losses | Value |
|----------------------------------|-----------|---------------------|----------------------|-----------|
| Government-sponsored enterprises | \$37,645 | \$ 10 | \$ - | \$37,655 |
| Corporate debt securities | 166,560 | 93 | (85) | 166,568 |
| Total | \$204,205 | \$ 103 | \$ (85) | \$204,223 |

| | December 31, 2015 | | | |
|----------------------------------|-------------------|------------------------------|-------------------------------|---------------|
| | Amortized Cost | Gross Unrealized Gains | Gross Unrealized Losses | Fair Value |
| U.S. Treasury securities | \$9,354 | \$ 1 | \$ (6) | \$9,349 |
| Government-sponsored enterprises | 22,055 | 1 | (9) | 22,047 |
| Corporate debt securities | 111,473 | 42 | (34) | 111,481 |
| Total | \$142,882 | \$ 44 | \$ (49) | \$142,877 |

One of the Company's available-for-sale securities held at September 30, 2016 had a maturity between one and two years. The remaining securities held at September 30, 2016 had maturity dates of less than one year. All of the Company's available-for-sale securities held at December 31, 2015 had maturity dates of less than one year. All available-for-sale securities in an unrealized loss position as of September 30, 2016 and December 31, 2015 were in a loss position for less than twelve months. There were no unrealized losses at September 30, 2016 or December 31, 2015 that the Company determined to be other-than-temporary.

4. 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. The Company undertook restructuring activities related to the acquisition of Raven. In connection with these restructuring activities, as part of the cost of acquisition, the Company established a restructuring liability attributed to an existing operating lease. During the three months ended June 30, 2016, the Company entered into an agreement to sublease a portion of the space subject to this operating lease. The Company will receive approximately \$1.3 million in sublease payments over its term, which ends at the same time as the original lease in February 2018. No sublease income was contemplated when the restructuring liability was recorded in 2008; therefore, the Company adjusted the liability to reflect the future sublease income during the three months ended June 30, 2016 and recorded an offset to research and development expenses of approximately \$1.3 million in the same period.

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

| | |
|---|---------|
| Accrual balance at December 31, 2015 | \$4,713 |
| Principal payments and other adjustments (net of sublease receipts) | (2,473) |
| Accrual balance at September 30, 2016 | \$2,240 |

5. Collaboration and Other Agreements

Janssen Biotech, Inc.

In December 2014, the Company entered into a collaboration and license agreement with Janssen Biotech, Inc. (Janssen) for the development and commercialization of MGD011 (also known as JNJ-64052781 or duvortuxizumab), a product candidate that incorporates the Company's proprietary DART® technology to simultaneously target CD19 and CD3 for the potential treatment of B-cell hematological malignancies (MGD011 Agreement). The Company

contemporaneously entered into an agreement with Johnson & Johnson Innovation - JJDC, Inc. (JJDC) under which JJDC agreed to purchase 1,923,077 new shares of the Company's common stock for proceeds of \$75.0 million. Upon closing the transaction in January 2015, the Company received a \$50.0 million upfront payment from Janssen as well as the \$75.0 million investment in the Company's common stock.

Under the collaboration and license agreement, the Company granted an exclusive license to Janssen to develop and commercialize MGD011. Following the Company's submission of the Investigational New Drug (IND) application for MGD011, Janssen became fully responsible for the development and commercialization of MGD011. Assuming successful development and commercialization, the agreement entitled the Company to receive up to \$205.0 million in development milestone payments, \$220.0 million in regulatory milestone payments and \$150.0 million in sales milestone payments. The Company determined that each potential future clinical and regulatory milestone is substantive. Although the sales milestones are not considered substantive, they will be 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 may elect to fund a portion of late-stage clinical development in exchange for a profit share with Janssen in the U.S. and Canada. If commercialized, the Company would be eligible to receive low double-digit royalties on any global net sales and has the option to co-promote the molecule with Janssen in the United States.

The Company evaluated the collaboration and license agreement with Janssen and determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under the collaboration and license agreement include the delivery of an exclusive license and research and development services during the preclinical research period (through the filing of the IND application for MGD011). The Company evaluated the collaboration and license agreement with Janssen and determined that the license and preclinical research and development activities each represented separate deliverables and were accounted for as separate units of accounting. The Company concluded that the license had standalone value to Janssen and was separable from the research and development services because the license was sublicensable, there were no restrictions as to Janssen's use of the license and Janssen or other third parties have significant research capabilities in this field. Thus, the total arrangement consideration for these two deliverables was allocated using the relative best estimate of selling price method to each deliverable. The best estimate of selling price for the exclusive license was determined using a discounted cash flow model that includes Level 3 fair value measurements. The best estimate of selling price for the research and development services was determined using third party evidence of other similar research and development arrangements, which are Level 2 fair value measurements.

The Company evaluated the stock purchase agreement and the collaboration and license agreement as one arrangement and determined that the stock purchase price of \$39.00 per share exceeded the fair value of the common stock by \$12.3 million. This excess was recognized in the same manner as the upfront payment allocated to the license and preclinical research and development activities. Of the total arrangement consideration of \$125.0 million, the Company allocated \$62.7 million to equity (representing the fair value of common stock purchased), \$62.3 million to the license and preclinical research and development activities, and a de minimis amount to the ongoing research and development activities. The Company submitted the IND application and therefore met its performance obligation during the year ended December 31, 2015.

In July 2015, Janssen dosed the first patient in an open-label Phase 1 study of MGD011 which triggered a \$10.0 million milestone to the Company. During the nine months ended September 30, 2015, the Company recognized revenues of approximately \$72.3 million under the MGD011 Agreement. There was no revenue recognized under the MGD011 Agreement during the three and nine months ended September 30, 2016.

In May 2016, the Company entered into a separate collaboration and license agreement with Janssen, a related party through ownership of the Company's common stock, for the development and commercialization of MGD015, a product candidate that incorporates the Company's proprietary DART technology to simultaneously target CD3 and an undisclosed tumor target for the potential treatment of various hematological malignancies and solid tumors

(MGD015 Agreement). The transaction closed in June 2016, and the Company received the \$75.0 million upfront payment from Janssen in July 2016.

Under the collaboration and license agreement, the Company granted an exclusive license to Janssen to develop and commercialize MGD015. Janssen will complete the IND-enabling activities and will be fully responsible for the future clinical development and commercialization of MGD015. Assuming successful development and commercialization, the agreement entitles the Company to receive up to \$100.0 million in development milestone payments, \$265.0 million in regulatory milestone payments and \$300.0 million in sales milestone payments. The Company determined that each potential future clinical and regulatory milestone is substantive. Although the sales milestones are not considered substantive, they will be 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 may elect to fund a portion of late-stage clinical development in exchange for a profit share with Janssen in the U.S. and Canada. If commercialized, the Company would be eligible to receive low double-digit royalties on any global net sales and has the option to co-promote the molecule with Janssen in the United States.

The Company evaluated the collaboration and license agreement with Janssen and determined that it is a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under the collaboration and license agreement include the delivery of an exclusive license and research and development services during the preclinical research period. The Company evaluated the collaboration and license agreement with Janssen and determined that the license and preclinical research and development activities each represented separate deliverables and were accounted for as two separate units of accounting. The Company concluded that the license had standalone value to Janssen and was separable from the research and development services because the license was sublicensable, there were no restrictions as to Janssen's use of the license and Janssen or other third parties have significant research capabilities in this field. Thus, the total arrangement consideration for these two deliverables was allocated using the best estimate of relative selling price method to each deliverable. The best estimate of selling price for the exclusive license was determined using information from the previous collaboration and license agreement with Janssen as well as other third party collaboration and license agreements, which are Level 2 fair value measurements. The best estimate of selling price for the research and development services was determined using other similar research and development arrangements, which are also Level 2 fair value measurements.

During the nine months ended September 30, 2016, the Company recognized revenues of \$75.0 million under the MGD015 Agreement.

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 DART technology to simultaneously engage CD32B and CD79B, which are two B-cell surface proteins. MGD010 is being developed for the treatment of autoimmune disorders. Upon execution of the agreement, Takeda made a non-refundable payment of \$15.0 million to the Company. Takeda had an option to obtain an exclusive worldwide license for MGD010 following the completion of a pre-defined Phase 1a study. Following the recent announcement of its therapeutic area re-prioritization, Takeda gave formal notification in September 2016 that it did not intend to exercise this option. As a result of Takeda not exercising the option, the Company regained worldwide development and commercialization rights to MGD010.

At the inception of the license and option agreement with Takeda, the Company evaluated it and determined that it was a revenue arrangement with multiple deliverables, or performance obligations. The Company's substantive performance obligations under the license and option agreement included exclusivity, research and development services through the Phase 1a study and delivery of a future license for an initial research compound. The Company

concluded that the MGD010 option was substantive and that the license fee payable upon exercise of the option was not a deliverable at the inception of the arrangement as there was considerable uncertainty that the option would be exercised. The Company determined that each potential future clinical and regulatory milestone was 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 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 its best estimate of selling price. The Company allocated \$10.0 million to the exclusivity clause to its technology 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., discounted 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 was being recognized over an initial 24-month period, which represented the expected period of development through the completion of a pre-defined Phase 1a study. During the first quarter of 2016, the Company determined that the development period would be extended by eight months, and prospectively adjusted the MGD010 option fee recognition period. 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. Upon the notification that Takeda would not exercise the option to obtain an exclusive worldwide license for MGD010 during the three months ended September 30, 2016, the Company's performance obligation to Takeda ceased, and the remaining deferred revenue under the MGD010 agreement was recognized in full.

The Company recognized revenue of approximately \$0.8 million and \$1.3 million under the MGD010 agreement during the three months ended September 30, 2016 and 2015, respectively. The Company recognized revenue of approximately \$2.1 million and \$6.8 million under the MGD010 agreement during the nine months ended September 30, 2016 and 2015, respectively. Revenue recognized during the nine months ended September 30, 2015, included a \$3.0 million milestone payment received upon initiation of a Phase 1a trial of MGD010. At September 30, 2016, no revenue was deferred under this agreement. At December 31, 2015, \$2.1 million of revenue was deferred under this agreement, all of which was current.

In September 2014, the Company and Takeda executed a research collaboration and license option agreement, which formalized the license for the initial research compound contemplated in the May 2014 arrangement. 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 allocated to this agreement 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. The Company is also entitled to receive reimbursements for research and development services provided to Takeda with respect to the initial research compound under a separate research plan. The Company recognized revenue of approximately \$0.5 million and \$1.1 million under this agreement during the three and nine months ended September 30, 2015, respectively. Takeda terminated its option to license the first program under this research collaboration agreement in 2015 and retains an option for three others.

Les Laboratoires Servier

In September 2012, the Company entered into a right-to-develop collaboration agreement with Les Laboratoires Servier and Institut de Recherches Servier (collectively, 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 (also known as S80880) and MGD007, as well as a third DART molecule, in all countries other than the United States, Canada, Mexico, Japan, South Korea and India.

Upon execution of the agreement, Servier made a nonrefundable payment of \$20.0 million to the Company. In addition, the Company will be eligible to receive up to \$65.0 million in license fees, \$98.0 million in clinical milestone payments, including \$5.0 million upon 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. In addition to these milestones, the Company and Servier will share Phase 2 and Phase 3 development costs. The Company has determined that each potential future clinical 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 from low double-digit to mid-teen royalties on net product sales in its territories.

The Company evaluated the research collaboration agreement with Servier and 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 preclinical 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 2014, the Company and Servier further refined the research plan related to the three DART molecules 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 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 months ended September 30, 2016, the Company recorded approximately \$1.0 million as an offset to research and development costs under this collaboration arrangement. No such offset to research and development costs was recorded during the three months ended September 30, 2015. During the nine months ended September 30, 2016 and 2015, the Company recorded approximately \$2.1 million and \$0.5 million as an offset to research and development costs under this collaboration arrangement, respectively.

The Company recognized revenue under this agreement of \$0.8 million and \$0.8 million during the three months ended September 30, 2016 and 2015, respectively. The Company recognized revenue under this agreement of \$2.5 million and \$2.6 million during the nine months ended September 30, 2016 and 2015, respectively. At September 30, 2016, \$11.9 million of revenue was deferred under this agreement, \$3.3 million of which was current and \$8.6 million

of which was non-current. At December 31, 2015, \$14.4 million of revenue was deferred under this agreement, \$3.3 million of which was current and \$11.1 million of which was non-current.

Green Cross Corporation

In June 2010, the Company entered into a collaboration agreement with Green Cross Corporation (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 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 evaluated the collaboration agreement with Green Cross and 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 separate units 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 is being 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 will 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 2014.

The Company recognized revenues of approximately \$0.1 million during each of the three-month periods ended September 30, 2016 and 2015 under this agreement. The Company recognized revenues of approximately \$0.3 million during each of the nine-month periods ended September 30, 2016 and 2015 under this agreement.

At September 30, 2016, \$1.7 million of revenue was deferred under this agreement, \$0.5 million of which was current and \$1.2 million of which was non-current. At December 31, 2015, \$2.0 million of revenue was deferred under this agreement, \$0.4 million of which was current and \$1.6 million of which was non-current.

NIAID Contract

The Company entered into a contract with the National Institute of Allergy and Infectious Diseases (NIAID), effective as of September 2015, to perform product development and to advance up to two DART molecules, including MGD014. Under this contract, the Company will develop these product candidates for Phase 1/2 clinical trials as

therapeutic agents, in combination with latency reversing treatments, to deplete cells infected with human immunodeficiency virus (HIV) infection. This contract includes a base period of \$7.5 million to support development of MGD014 through IND application submission with the FDA, as well as up to \$17.0 million in additional development funding via NIAID options. Should NIAID fully exercise such options, the Company could receive total payments of up to \$24.5 million. The total potential period of performance under the award is from September 15, 2015 through September 14, 2022. The Company recognized \$1.2 million and \$4.3 million in revenue under this contract during the three and nine months ended September 30, 2016, respectively.

6. Stock-Based Compensation

Under the provisions of the Company's 2013 Stock Incentive Plan (2013 Plan), 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. During the nine months ended September 30, 2016, the maximum number of shares of common stock authorized to be issued by the Company under the 2013 Plan was increased to 5,375,064. As of September 30, 2016, there were options to purchase an aggregate of 2,621,944 shares of common stock outstanding at a weighted average exercise price of \$26.61 per share under the 2013 Plan.

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

| | Three Months Ended | | Nine Months Ended | |
|--|--------------------|--------------------|--------------------|--------------------|
| | September 30, 2016 | September 30, 2015 | September 30, 2016 | September 30, 2015 |
| Research and development | \$1,403 | \$916 | \$4,243 | \$2,607 |
| General and administrative | 1,600 | 1,182 | 4,883 | 3,024 |
| Total stock-based compensation expense | \$3,003 | \$2,098 | \$9,126 | \$5,631 |

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, | |
|-------------------------|---------------------------------|-------------|
| | 2016 | 2015 |
| Expected dividend yield | 0% | 0% |
| Expected volatility | 63.7 % - 67.7 % | 74 % - 75 % |
| Risk-free interest rate | 1.2% - 2.1% | 1.6% - 2.1% |
| Expected term | 6.25 years | 6.25 years |

The following table summarizes stock option and restricted stock unit (RSU) activity during the nine months ended September 30, 2016:

| Shares | Weighted-Average Exercise Price | Weighted-Average Remaining Contractual Term (Years) | Aggregate Intrinsic Value (in thousands) |
|--------|---------------------------------|---|--|
|--------|---------------------------------|---|--|

Edgar Filing: MACROGENICS INC - Form 10-Q

| | | | | |
|---------------------------------|------------|----------|-----|-----------|
| Outstanding, December 31, 2015 | 4,146,064 | \$ 16.90 | 7.4 | |
| Granted | 346,524 | 22.50 | | |
| Exercised | (469,442) | 3.07 | | |
| Forfeited or expired | (166,494) | 26.50 | | |
| Outstanding, September 30, 2016 | 3,856,652 | 18.67 | 7.2 | \$ 45,214 |
| As of September 30, 2016: | | | | |
| Exercisable | 2,160,650 | 12.86 | 6.1 | 37,400 |
| Vested and expected to vest | 3,654,153 | 18.32 | 7.1 | 44,082 |

The weighted-average grant-date fair value of options granted for the nine months ended September 30, 2016 was \$14.81. The total intrinsic value of options exercised during the nine months ended September 30, 2016 was approximately \$9.6 million, and the total cash received for options exercised was approximately \$1.4 million. The total fair value of shares vested in the nine months ended September 30, 2016 was approximately \$8.8 million. As of September 30, 2016, the total unrecognized compensation expense related to non-vested stock options, net of related forfeiture estimates, was approximately \$24.2 million, which the Company expects to recognize over a weighted-average period of approximately three years.

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 stock equivalents outstanding for the period. The treasury stock method is used to determine the dilutive effect of the Company's stock option grants. 1,458,168 and 1,916,156 stock options (common stock equivalents) were excluded from the calculation of diluted income (loss) per share for the three months ended September 30, 2016 and 2015, respectively, because their inclusion would have been anti-dilutive. 1,424,980 and 911,304 stock options were excluded from the calculation of diluted income per share for the nine months ended September 30, 2016 and 2015, respectively, because their inclusion would have been anti-dilutive.

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|-------------|------------------------------------|------------|
| | 2016 | 2015 | 2016 | 2015 |
| Numerator: | | | | |
| Net income (loss) used for calculation of basic and diluted EPS | \$(33,846) | \$(15,442) | \$(23,745) | \$8,311 |
| Denominator: | | | | |
| Weighted average shares outstanding, basic | 34,766,440 | 33,339,163 | 34,629,330 | 30,952,458 |
| Effect of dilutive securities: | | | | |
| Stock options and restricted stock units | - | - | - | 2,007,775 |
| Weighted average shares outstanding, diluted | 34,766,440 | 33,339,163 | 34,629,330 | 32,960,233 |
| Net income (loss) per share, basic | \$(0.97) | \$(0.46) | \$(0.69) | \$0.27 |
| Net income (loss) per share, diluted | \$(0.97) | \$(0.46) | \$(0.69) | \$0.25 |

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 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, 2015.

Overview

We are a biopharmaceutical company focused on discovering and developing innovative antibody-based therapeutics for the treatment of cancer as well as various autoimmune disorders and infectious diseases. We currently have a pipeline of product candidates in human clinical testing, primarily against different types of cancers, which have been created primarily using our proprietary technology platforms. We believe our programs have the potential to have a meaningful effect on treating patients' unmet medical needs as monotherapy or, in some cases, in combination with other therapeutic agents.

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 preclinical 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 public and private offerings of our securities, collaborations, government grants and government contracts. Although it is difficult to predict our funding requirements, based upon our current operating plan, we anticipate that our cash, cash equivalents and marketable securities as of September 30, 2016, combined with collaboration payments we anticipate receiving, will enable us to fund our operations for approximately two years, assuming all of our programs and collaborations advance as currently contemplated.

Through September 30, 2016, we had an accumulated deficit of \$257.9 million. We expect that over the next several years this deficit will increase as we increase our expenditures in research and development in connection with our ongoing activities with several clinical trials.

Strategic Collaborations and Licenses

We pursue a balanced approach between product candidates that we develop ourselves and those that we develop through collaborators. Under our current strategic collaborations, we have received significant non-dilutive funding to date and continue to have rights to additional funding upon achievement of key product development and regulatory milestones, and royalties and sales milestones upon the commercial sale of products. Our most significant strategic collaborations include the following:

- Janssen. In December 2014, we entered into a collaboration and license agreement with Janssen for the development and commercialization of MGD011, a product candidate that incorporates our proprietary DART technology to simultaneously target CD19 and CD3 for the potential treatment of B-cell hematological malignancies. We contemporaneously entered into an agreement with JJDC, an affiliate of Janssen, under which JJDC agreed to purchase 1,923,077 new shares of our common stock for proceeds of \$75.0 million. Upon closing, we received a \$50.0 million upfront payment from Janssen as well as the \$75.0 million investment in our common stock. Janssen is leading the development of this product candidate, subject to our options to co-promote the product in the United States and Canada and to invest in later-stage development in exchange for a United States and Canada profit-share. Janssen initiated a human clinical trial in 2015 for a variety of B-cell hematological malignancies, including diffuse-large B cell lymphoma, follicular lymphoma, mantle-cell lymphoma, chronic lymphocytic leukemia and acute lymphoblastic leukemia. The initiation of this trial triggered a \$10.0 million milestone payment to us. Assuming

successful development and commercialization, we could receive up to an additional \$565.0 million in clinical, regulatory and commercialization milestone payments. If commercialized, we would be eligible to receive low double-digit royalties on any global net sales.

In May 2016, we entered into a separate collaboration and license agreement with Janssen for the development and commercialization of MGD015, a product candidate that incorporates our proprietary DART technology to simultaneously target CD3 and an undisclosed tumor target for the potential treatment of various hematological malignancies and solid tumors. The transaction closed in June 2016, and we received the \$75.0 million upfront payment from Janssen in July 2016. Under the collaboration and license agreement, we granted an exclusive license to Janssen to develop and commercialize MGD015. Janssen will complete the IND-enabling activities and will be fully responsible for the future clinical development and commercialization of MGD015. Assuming successful development and commercialization, the agreement entitles us to receive up to \$665.0 million in development, regulatory and sales milestone payments. If commercialized, we would be eligible to receive low double-digit royalties on any global net sales and have the option to co-promote the molecule with Janssen in the United States.

Servier. In September 2012, we entered into a license 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. Additionally, assuming exercise of its options, Servier may share Phase 2 and Phase 3 development costs and would be obligated to pay us low double-digit to mid-teen royalties on product sales in its territories.

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 two \$5.0 million milestone payments from Servier in connection with the IND applications for MGD006 and MGD007 clearing the 30-day review period by the U.S. Food and Drug Administration (FDA).

In addition, our technology platforms are generally applicable to a wide variety of potential therapeutic uses. Our core focus is in developing potential cancer treatments, but we also pursue programs related to autoimmune and inflammatory disorders as well as infectious diseases. For these therapeutic areas, in particular, we complement our internal expertise and capabilities with strategic collaborators that may help us advance those programs. For example, we created MGD010, a DART molecule targeting two antigens found on B cells, CD32B and CD79B, that we believe may have potential applicability in a wide variety of autoimmune and inflammatory disorders. We had initially chosen to collaborate with Takeda with respect to this program, but they have since strategically re-prioritized their therapeutic areas of interest and as a result we regained the rights to MGD010. We plan to continue to move this program forward and will consider the appropriate balance between internal development and strategic collaborations. Similarly, we created a DART molecule targeting CD3 and the HIV envelope protein to potentially eliminate latent reservoirs of HIV in patients who are taking anti-retroviral therapy. We receive funding under this program from the National Institute of Allergy and Infectious Diseases, one of the National Institutes of Health, and collaborate in the execution of this program with the University of North Carolina, Chapel Hill and Duke University, among others. Finally, teplizumab is an immunomodulatory anti-CD3 monoclonal antibody in our portfolio. This molecule is being evaluated in a Phase 2 study for potential application to patients at risk of developing Type 1 diabetes. We have elected to collaborate with NIDDK/TrialNet to execute this clinical trial. In addition, we continue to seek strategic collaborations for the advancement of this program that could include joint funding, spinning the program out into a new company, divesting the program or pursuing other transaction structures that we feel would be aligned with our strategic objectives and provide financial consideration commensurate with our expectations of value for the program.

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, 2015. There have been no material changes to our critical accounting policies during the three months ended September 30, 2016.

Results of Operations

Revenue

The following represents a comparison of our revenue for the three and nine months ended September 30, 2016 and 2015:

| | Three Months Ended September 30, | | Increase/(Decrease) | |
|--|--|------|---------------------|--|
| | 2016 | 2015 | | |
| | (dollars in millions) | | | |

| | | | | |
|---------------------------------------|-------|--------|------------|--------|
| Revenue from collaborative agreements | \$2.0 | \$14.7 | \$ (12.7) | (86)% |
| Revenue from government agreements | 1.2 | - | 1.2 | NA |
| Total revenue | \$3.2 | \$14.7 | \$ (11.5) | (78)% |

| | Nine Months Ended September 30, | | Increase/(Decrease) | |
|--|--|------|---------------------|--|
| | 2016 | 2015 | | |
| | (dollars in millions) | | | |

| | | | | |
|---------------------------------------|--------|--------|-----------|--------|
| Revenue from collaborative agreements | \$82.4 | \$91.4 | \$ (9.0) | (10)% |
| Revenue from government agreements | 4.4 | 1.2 | 3.2 | 254 % |
| Total revenue | \$86.8 | \$92.6 | \$ (5.8) | (6)% |

The decrease in collaboration revenue of \$12.7 million for the three months ended September 30, 2016 compared to the three months ended September 30, 2015 is primarily due to the \$10.0 million milestone payment from Janssen recognized in the third quarter of 2015 and the decrease in revenue recognition related to the Boehringer Ingelheim International (Boehringer) agreement. Revenue under the Boehringer agreement decreased because the development period, and therefore the related revenue recognition period, was completed in September 2015.

The decrease in collaboration revenue of \$9.0 million for the nine months ended September 30, 2016 compared to the nine months ended September 30, 2015 is primarily due to decreases in revenue recognition related to the Boehringer and Takeda MGD010 agreements. Revenue under the Boehringer agreement decreased because the development period, and therefore the related revenue recognition period, was completed in September 2015. Revenue from the Takeda agreement decreased primarily due to a \$3.0 million milestone being recognized during the nine months ended September 30, 2015. These decreases were partially offset by the \$75.0 million in revenue recognized during the nine months ended September 30, 2016 under the Janssen MGD015 agreement and a \$2.0 million milestone received from Pfizer, Inc. during the nine months ended September 30, 2016 compared to \$72.3 million recognized during the nine months ended September 30, 2015 under the Janssen MGD011 agreement.

Revenue from government agreements increased for the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015 primarily due to revenue from the NIAID contract which

began in September 2015.

Research and Development Expense

The following represents a comparison of our research and development expense for the three and nine months ended September 30, 2016 and 2015:

| | Three Months Ended September 30, | | Increase/(Decrease) | | |
|--|--|--------|---------------------|------|----|
| | 2016 | 2015 | | | |
| | (dollars in millions) | | | | |
| Margetuximab | \$9.3 | \$8.7 | \$ 0.6 | 7 | % |
| Enoblituzumab | 5.3 | 3.5 | 1.8 | 51 | % |
| MGD006 ^a | 0.5 | 0.8 | (0.3) | (38 | %) |
| MGD007 | 0.9 | 1.3 | (0.4) | (31 | %) |
| MGD009 | 0.9 | 1.1 | (0.2) | (18 | %) |
| MGD010 | 2.4 | 1.8 | 0.6 | 33 | % |
| MGD011 ^a | (1.8) | 0.4 | (2.2) | (550 | %) |
| Immune checkpoint programs ^b | 6.6 | - | 6.6 | N/A | |
| Other pre-clinical and clinical programs, collectively | 6.2 | 6.5 | (0.3) | (5 | %) |
| Total research and development expense | \$30.3 | \$24.1 | \$ 6.2 | 26 | % |

| | Nine Months Ended September 30, | | Increase/(Decrease) | | |
|--|--|--------|---------------------|-----|----|
| | 2016 | 2015 | | | |
| | (dollars in millions) | | | | |
| Margetuximab | \$29.1 | \$28.1 | \$ 1.0 | 4 | % |
| Enoblituzumab | 13.9 | 8.5 | 5.4 | 64 | % |
| MGD006 ^a | 2.4 | 1.8 | 0.6 | 33 | % |
| MGD007 | 2.5 | 2.7 | (0.2) | (7 | %) |
| MGD009 | 2.4 | 3.1 | (0.7) | (23 | %) |
| MGD010 | 5.7 | 6.1 | (0.4) | (7 | %) |
| MGD011 ^a | 0.3 | 1.8 | (1.5) | (83 | %) |
| Immune checkpoint programs ^b | 17.4 | - | 17.4 | N/A | |
| Other pre-clinical and clinical programs, collectively | 17.3 | 16.1 | 1.2 | 7 | % |
| Total research and development expense | \$91.0 | \$68.2 | \$ 22.8 | 33 | % |

a - Expenses are shown net of reimbursements from partner.

b - Immune checkpoint program expenses for the three and nine months ended September 30, 2015 were included in Other preclinical and clinical programs, collectively.

Edgar Filing: MACROGENICS INC - Form 10-Q

During the three and nine months ended September 30, 2016 our research and development expense increased by \$6.2 million and \$22.8 million, respectively, compared to the three and nine months ended September 30, 2015. This increase was due primarily to increased activity in our preclinical immune checkpoint programs, including MGD013, the initiation of two Phase 1 clinical trials combining enoblituzumab with other compounds and the addition of the NIAID MGD014 contract. During the three and nine months ended September 30, 2016, the increase was partially offset by \$1.8 million and \$1.9 million, respectively, in cost reimbursement from Janssen under the MGD011 Agreement. During the nine months ended September 30, 2016, the increase was also partially offset by a \$1.3 million reduction in research and development expense related to the adjustment of the lease exit liability (see Note 4 of the Notes to the Consolidated Financial Statements for additional information).

General and Administrative Expense

The following represents a comparison of our general and administrative expense for the three and nine months ended September 30, 2016 and 2015:

| | Three Months Ended September 30, | | Increase/(Decrease) | |
|--|--|------|---------------------|--|
| | 2016 | 2015 | | |
| | (dollars in millions) | | | |

| | | | | | |
|------------------------------------|-------|-------|--------|----|---|
| General and administrative expense | \$7.2 | \$6.0 | \$ 1.2 | 20 | % |
|------------------------------------|-------|-------|--------|----|---|

| | Nine Months Ended September 30, | | Increase/(Decrease) | |
|--|--|------|---------------------|--|
| | 2016 | 2015 | | |
| | (dollars in millions) | | | |

| | | | | | |
|------------------------------------|--------|--------|--------|----|---|
| General and administrative expense | \$20.6 | \$16.1 | \$ 4.5 | 28 | % |
|------------------------------------|--------|--------|--------|----|---|

General and administrative expense increased for the three and nine months ended September 30, 2016 compared to 2015 primarily due to increased staff, recruiting costs, and stock-based compensation expense.

Other Income (Expense)

The increase in other income for the three and nine months ended September 30, 2016 compared to the three and nine months ended September 30, 2015 is primarily due to an increase in interest income earned on marketable securities.

Liquidity and Capital Resources

We have historically financed our operations primarily through public and private offerings of equity, upfront fees, milestone payments and license option fees from collaborators and reimbursement through government grants and contracts. As of September 30, 2016, we had \$314.1 million in cash, cash equivalents and marketable securities. In addition to our existing cash, cash equivalents and marketable securities, we are eligible to receive additional reimbursement from our collaborators for certain 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.

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 preclinical 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, cash equivalents and marketable securities as of September 30, 2016, as well as other collaboration payments we anticipate receiving, will enable us to fund our operations for approximately two years, assuming all of our programs and collaborations advance as currently contemplated.

Cash Flows

The following table represents a summary of our cash flows for the nine months ended September 30, 2016 and 2015:

| | Nine Months Ended September 30, 2016 2015 (dollars in millions) | |
|--|--|---------|
| Net cash provided by (used in): | | |
| Operating activities | \$(15.3) | \$10.5 |
| Investing activities | (72.3) | (6.4) |
| Financing activities | 1.4 | 204.1 |
| Net increase (decrease) in cash and cash equivalents | \$(86.2) | \$208.2 |

Operating Activities

Net cash provided by (used in) operating activities reflects, among other things, the amounts used to run our clinical trials and preclinical activities. The difference between net cash used in operating activities during the nine months ended September 30, 2016 and net cash provided by operating activities during the nine months ended September 30, 2015 was primarily due to the factors described in Results of Operations above.

Investing Activities

Net cash used in investing activities during the nine months ended September 30, 2016 is primarily due to investing our cash in marketable securities and making leasehold improvements to our facilities. Net cash used in investing activities during the nine months ended September 30, 2015 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, 2016 reflects cash from stock option exercises. Net cash provided by financing activities for the nine months ended September 30, 2015 included net proceeds from the JJDC investment and cash from stock option exercises.

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.

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. We also seek to maximize income from our investments without assuming significant risk. 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, 2016, we had cash, cash equivalents and marketable securities of \$314.1 million. Our primary exposure to market risk is related to changes in interest rates. Due to the short-term maturities of our cash equivalents and marketable securities and the low risk profile of our marketable securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and marketable securities. We have the ability to hold our marketable securities until maturity, and we therefore do not expect a change in market interest rates to affect our operating results or cash flows to any significant degree.

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, 2016. Our disclosure controls and procedures are designed to provide reasonable assurance that the information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 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 three months ended September 30, 2016, 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, 2015. See also, "Forward-Looking Statements" included in this Quarterly Report on Form 10-Q.

Item 6. Exhibits

- 3.1 Restated Certificate of Incorporation of the Company and Certificate of Correction to the Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibits 3.1 and 3.3, respectively, to the Company's Current Report on Form 8-K filed on October 18, 2013)
 - 3.2 Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013)
 - 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
-

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

Dated: November 2, 2016

EXHIBIT INDEX

Exhibit Page Number

| | |
|---------|---|
| 3.1 | Restated Certificate of Incorporation of the Company and Certificate of Correction to the Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibits 3.1 and 3.3, respectively, to the Company's Current Report on Form 8-K filed on October 18, 2013) |
| 3.2 | Amended and Restated By-Laws of the Company (incorporated by reference to Exhibit 3.4 to the Registration Statement on Form S-1 (File No. 333-190994) filed by the Company on October 1, 2013) |
| 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 |