

MACROGENICS INC  
Form 10-Q  
November 12, 2013  
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**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 quarterly period ended September 30, 2013**

**Commission File Number 001-36112**

**MACROGENICS, INC.**

**(Exact name of registrant)**

<b>Delaware</b>	<b>06-1591613</b>
<b>(State of organization)</b>	<b>(I.R.S. Employer Identification Number)</b>
<b>9640 Medical Center Drive, Rockville, Maryland 20850</b>	

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(Address of principal executive offices and zip code)

(301) 251-5172

(Registrant's telephone number)

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 the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐

Non-accelerated filer ☒ Smaller reporting company ☐

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

The number of shares of the registrant's common stock outstanding on October 31, 2013 was 25,020,288.

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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****MACROGENICS, INC.****CONSOLIDATED BALANCE SHEETS**

	<b>September 30, 2013</b>	<b>December 31, 2012</b>
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 33,569,198	\$ 47,743,155
Accounts receivable	2,281,282	2,046,219
Prepaid expenses	1,103,449	137,634
Total current assets	36,953,929	49,927,008
Restricted cash	404,850	404,850
Property and equipment, net	4,469,882	3,267,796
Other assets	147,246	147,246
Total assets	\$ 41,975,907	\$ 53,746,900
<b>Liabilities and stockholders equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,798,228	\$ 3,739,125
Accrued expenses	939,811	1,237,025
Lease exit liability current	1,229,454	628,768
Deferred revenue current	21,298,318	24,123,176
Total current liabilities	25,265,811	29,728,094
Lease exit liability	8,378,184	9,445,171
Deferred rent liability	2,888,688	2,801,653
Preferred stock warrant liability	679,296	52,947
Deferred revenue, net of current portion	8,812,342	19,956,343
Total liabilities	46,024,321	61,984,208
Stockholders equity (deficit):		
Series A-1 convertible preferred stock, \$0.01 par value 26,874,792 shares authorized, 26,874,792 shares issued and outstanding at September 30, 2013 and December 31, 2012; aggregate liquidation preference of \$27,000,000 at September 30, 2013 and December 31, 2012	268,748	268,748
Series A-2 convertible preferred stock, \$0.01 par value 7,364,582 shares authorized, 7,364,582 shares issued and outstanding at September 30, 2013 and December 31, 2012; aggregate liquidation preference of \$7,000,000 at	73,646	73,646

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September 30, 2013 and December 31, 2012		
Series B convertible preferred stock, \$0.01 par value 71,401,237 shares authorized, 71,401,237 shares issued and outstanding at September 30, 2013 and December 31, 2012; aggregate liquidation preference of \$31,000,000 at September 30, 2013 and December 31, 2012	714,012	714,012
Series C convertible preferred stock, \$0.01 par value 110,952,217 shares authorized, 110,952,217 shares issued and outstanding at September 30, 2013 and December 31, 2012; aggregate liquidation preference of \$45,000,000 at September 30, 2013 and December 31, 2012	1,109,522	1,109,522
Series D-1 convertible preferred stock, \$0.01 par value 30,000,000 shares authorized, 14,446,227 shares issued and outstanding at September 30, 2013 and December 31, 2012; aggregate liquidation preference of \$9,400,000 at September 30, 2013 and December 31, 2012	144,462	144,462
Series D-2 convertible preferred stock, \$0.01 par value 75,000,000 shares authorized, 63,681,176 shares issued and outstanding at September 30, 2013 and December 31, 2012; aggregate liquidation preference of \$41,500,000 at September 30, 2013 and December 31, 2012	636,812	636,812
Common stock, \$0.01 par value 425,000,000 shares authorized, 2,124,624 and 1,098,914 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	21,246	10,989
Treasury stock, at cost; 14,381 shares at September 30, 2013 and December 31, 2012	(57,742)	(57,742)
Additional paid-in capital	165,569,134	164,334,646
Accumulated deficit	(172,528,254)	(175,472,403)
Total stockholders' equity (deficit)	(4,048,414)	(8,237,308)
Total liabilities and stockholders' equity (deficit)	\$ 41,975,907	\$ 53,746,900

See accompanying notes.

**Table of Contents****MACROGENICS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)****(unaudited)**

	<b>Three Months Ended September 30,</b>		<b>September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
<b>Revenues:</b>				
Revenue from collaborative research	\$ 20,111,173	\$ 15,532,680	\$ 42,015,994	\$ 50,283,510
Grant revenue	120,895	548,864	1,112,238	3,744,047
Total revenues	20,232,068	16,081,544	43,128,232	54,027,557
<b>Costs and expenses:</b>				
Research and development	11,087,919	11,968,253	32,233,828	36,924,987
General and administrative	1,986,555	1,514,334	7,322,974	6,640,740
Total costs and expenses	13,074,474	13,482,587	39,556,802	43,565,727
Income (loss) from operations	7,157,594	2,598,957	3,571,430	10,461,830
Other income (expense)	(553,612)	1,557	(627,281)	4,752
Net comprehensive income (loss)	\$ 6,603,982	\$ 2,600,514	\$ 2,944,149	\$ 10,466,582
Basic net income (loss) per common share	\$ 0.14	\$ 0.00	\$ 0.00	\$ 0.00
Diluted net income (loss) per common share	\$ 0.01	\$ 0.00	\$ 0.00	\$ 0.00
Basic weighted average number of common shares	1,184,507	1,092,307	1,463,798	1,078,145
Diluted weighted average number of common shares	21,242,978	21,502,424	21,908,859	21,412,848

*See accompanying notes.*

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**MACROGENICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
<b>Operating activities</b>		
Net income	\$ 2,944,149	\$ 10,466,582
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		
Depreciation expense	834,615	722,496
Share-based compensation	393,561	628,796
Fair value adjustment of warrant liability	626,349	
Changes in operating assets and liabilities:		
Accounts receivable	(235,063)	(2,713,429)
Prepaid expenses	(965,815)	(69,231)
Accounts payable	(1,940,897)	(5,444,288)
Accrued expenses	(297,214)	53,860
Lease exit liability	(466,301)	(395,694)
Deferred revenue	(13,968,859)	(27,935,268)
Deferred rent	87,035	404,727
Net cash used in operating activities	(12,988,440)	(24,281,449)
<b>Cash flows from investing activities</b>		
Purchases of property and equipment	(2,036,700)	(530,136)
Net cash used in investing activities	(2,036,700)	(530,136)
<b>Cash flows from financing activities</b>		
Proceeds from issuance of common stock	851,183	44,309
Net cash provided by financing activities	851,183	44,309
Net change in cash and cash equivalents	(14,173,957)	(24,767,276)
Cash and cash equivalents at beginning of period	47,743,155	55,218,361
Cash and cash equivalents at end of period	\$ 33,569,198	\$ 30,451,085

*See accompanying notes.*

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**MACROGENICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Overview and Basis of Presentation**

MacroGenics, Inc. (the Company) was incorporated in Delaware on August 14, 2000. The Company is a clinical-stage biopharmaceutical company focused on discovering and developing innovative monoclonal antibody-based therapeutics for the treatment of cancer and autoimmune diseases. The Company generates its pipeline of product candidates from its proprietary suite of next-generation antibody technology platforms which it believes improve the performance of monoclonal antibodies and antibody-derived molecules. These product candidates, which the Company has identified through its understanding of disease biology and immune-mediated mechanisms, may address disease-specific challenges which are not currently being met by existing therapies. The Company creates both differentiated molecules that are directed to novel cancer targets, as well as bio-betters which are drugs designed to improve upon marketed medicines.

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 financial statements have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these consolidated financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Prospectus filed with the SEC pursuant to Rule 424(b)(4) on October 11, 2013 (the Prospectus). In the opinion of the Company's management, the consolidated unaudited interim consolidated financial statements reflect all adjustments necessary to present fairly the results of operations for the three and nine months ended September 30, 2013 and 2012, the Company's financial position as of September 30, 2013, and the cash flows for the nine months ended September 30, 2013 and 2012. These adjustments are of a normal recurring nature. The results of operations for the three and nine months ended September 30, 2013 are not necessarily indicative of future financial results.

The Company currently operates in one operating segment. Operating segments are defined as components of an enterprise about which separate discrete information is available for the chief operating decision maker, or decision making group, in deciding how to allocate resources and assessing performance. The Company views its operations and manages its business in one segment, which is developing monoclonal antibody-based therapeutics for cancer, autoimmune and infectious diseases.

On October 16, 2013, the Company completed an initial public offering (IPO) of its common stock, which resulted in the sale of 5,750,000 shares, including all additional shares available to cover over-allotments, at a price of \$16.00 per share. The Company received net proceeds before expenses from the IPO of \$85.6 million after deducting underwriting discounts and commissions paid by the Company.

**2. Summary of Significant Accounting Policies**

***Use of Estimates***

The preparation of the financial statements in accordance with GAAP requires the Company to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, revenues and expenses, and



related disclosure of contingent assets and liabilities. In preparing these consolidated financial statements, management has made its best estimates and judgments of certain amounts included in the financial statements, giving due consideration to materiality. On an ongoing basis, the Company evaluates its estimates, including those related to revenue recognition, fair values of assets, convertible preferred stock and common stock, preferred stock warrant liability, income taxes, pre-clinical study and clinical trial accruals and other contingencies. Management bases its estimates on historical experience or on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

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In addition, through September 30, 2013, the Company utilized estimates and assumptions in determining the fair value of its common stock. The Company granted stock options at exercise prices not less than the fair value of its common stock as determined by the board of directors, with input from management. Management uses contemporaneous valuations in estimating the fair value of its common stock. The board of directors has determined the estimated fair value of the common stock based on a number of objective and subjective factors, including external market considerations affecting the biotechnology industry and the historic prices at which the Company sold shares of its preferred stock.

### ***Cash and Cash Equivalents***

The Company considers all investments in highly liquid financial instruments with an original maturity of three months or less at the date of purchase to be cash equivalents. Cash and cash equivalents consist of certificates of deposit and investment in money market funds with commercial banks and financial institutions. Cash equivalents are stated at amortized cost, plus accrued interest, which approximates fair value.

### ***Accounts Receivable***

Accounts receivable that management has the intent and ability to collect are reported in the consolidated balance sheets at outstanding amounts, less an allowance for doubtful accounts. The Company writes off uncollectible receivables when the likelihood of collection is remote.

The Company evaluates the collectability of accounts receivable on a regular basis. The allowance, if any, is based upon various factors including the financial condition and payment history of customers, an overall review of collections experience on other accounts and economic factors or events expected to affect future collections experience. No allowance was recorded as of September 30, 2013 or December 31, 2012, as the Company has a history of collecting on all outstanding accounts.

### ***Deferred Initial Public Offering Costs***

Deferred IPO costs as of September 30, 2013, consisted of legal, accounting, printing and filing fees were capitalized. The deferred costs are included in prepaid expenses on the consolidated balance sheets. The deferred offering costs were offset against the IPO proceeds received upon the completion of the offering in October 2013.

### ***Restricted Cash***

The Company is required to maintain certificates of deposit that serve as collateral for various operating leases and corporate credit card accounts. Amounts classified as restricted cash on the consolidated balance sheets are \$404,850 at September 30, 2013 and December 31, 2012.

### ***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, 2013 and December 31, 2012, due to their short-term maturities. The Company accounts for recurring and non-recurring fair value measurements in accordance with the Financial Accounting Standards Board (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.

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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:

<b>Fair Value Measurements at September 30, 2013</b>				
		<b>Quoted Prices in Active Markets for Identical Assets</b>		<b>Significant Other Unobservable Inputs</b>
	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Assets:</b>				
Cash and cash equivalents	\$ 7,522,029	\$ 7,522,029	\$	\$
Money market funds	26,047,169	26,047,169		
Restricted cash	404,850	404,850		
<b>Total assets</b>	<b>\$ 33,974,048</b>	<b>\$ 33,974,048</b>	<b>\$</b>	<b>\$</b>
<b>Liabilities:</b>				
Preferred stock warrant liability	\$ (679,296)	\$	\$	\$ (679,296)

<b>Fair Value Measurements at December 31, 2012</b>				
		<b>Quoted Prices in Active Markets for Identical Assets</b>		<b>Significant Other Unobservable Inputs</b>
	<b>Total</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Assets:</b>				
Cash and cash equivalents	\$ 18,695,197	\$ 18,695,197	\$	\$
Money market funds	29,047,958	29,047,958		
Restricted cash	404,850	404,850		
<b>Total assets</b>	<b>\$ 48,148,005</b>	<b>\$ 48,148,005</b>	<b>\$</b>	<b>\$</b>
<b>Liabilities:</b>				
Preferred stock warrant liability	\$ (52,947)	\$	\$	\$ (52,947)

As of December 31, 2012, the Company transferred its money market funds from Level 2 to Level 1 because the inputs are now based upon a quoted market price.

The Company's Level 1 securities primarily consist of restricted cash, cash equivalents and money market funds. The Company determines the estimated fair value for its Level 1 securities using quoted (unadjusted) prices for identical

assets or liabilities in active markets.

The Company determines the estimated fair value for its Level 2 securities using the following methods: quoted prices for similar assets/liabilities in active markets, inputs other than quoted prices that are observable for the asset/liability (e.g., interest rates, yield curves volatilities, default rates, etc.) and inputs that are derived principally from or corroborated by other observable market data.

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The following table provides a rollforward of the Company's preferred stock warrant liability, which was the only financial instrument measured at fair value on a recurring basis using significant unobservable inputs (Level 3) as defined in ASC 820:

Balance at December 31, 2012	\$ (52,947)
Total unrealized gains (losses) included in earnings	(626,349)
Balance at September 30, 2013	\$ (679,296)

In order to estimate the fair value of the preferred stock purchase warrants, the business enterprise value was established based on a discounted cash flow model (income approach). The Company utilized an option pricing method to value the shares using a contingent claims analysis, which applies a series of call options whose inputs reflect the liquidation preferences and conversion behavior of the different classes of equity. After the equity value of the business enterprise was determined, the total equity value is allocated to the various equity instruments such as preferred stock, stock options and preferred stock purchase warrants. Key management estimates relate to the time period to liquidation and conversion behavior of a particular class of stockholders. The business enterprise value includes assumptions related to product approval, market penetration and costs to develop the product. Significant changes to these assumptions would result in increases/decreases to the fair value of the outstanding warrants.

The total unrealized gains (losses) on the preferred stock warrants included in earnings is included as a component of other income (expense) in the consolidated statement of operations and comprehensive income.

***Concentration of Credit Risk***

Substantially all of the Company's cash and cash equivalents are maintained with major financial institutions in the United States. Deposits held with banks may exceed the amount of insurance provided on such deposits. Generally, these deposits may be redeemed upon demand and, therefore, bear minimal risk.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, and accounts receivable. The counterparties are various corporations, financial institutions and government agencies of high credit standing.

For the three and nine months ended September 30, 2013 and 2012, all of the Company's grant revenue was related to contracts and research grants received from U.S. government agencies. Collaborations with Les Laboratoires Servier and Institut de Recherches Servier (collectively, Servier), Boehringer Ingelheim GmbH (Boehringer), Gilead Sciences, Inc. (Gilead), Pfizer, Inc. (Pfizer) and Eli Lilly & Co. (Eli Lilly) account for all other revenue. All outstanding receivables are due from Gilead, Pfizer, Boehringer, Eli Lilly, and U.S. government agencies.

The following table represents the percentage of all significant revenue earned in the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Servier	71.3%	14.2%	58.8%	12.6%
Boehringer	11.5%	15.6%	15.9%	17.2%

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Gilead	10.9%	0.0%	13.7%	0.0%
Pfizer	4.5%	7.7%	7.3%	7.4%
Government Agencies	0.6%	3.5%	2.6%	6.9%
Eli Lilly	0.9%	59.0%	1.6%	55.7%

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The following table represents the percentage of all significant accounts receivable:

	September 30, 2013	December 31, 2012
Gilead	51.2%	
Pfizer	22.6%	45.4%
Boehringer	11.1%	18.0%
Eli Lilly	11.0%	28.2%
Government Agencies	4.0%	8.4%

***Property and Equipment***

Property and equipment are stated at cost. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to operations. Repairs and maintenance costs are expensed as incurred. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Computer equipment	3 years
Software	3 years
Furniture	10 years
Laboratory and office equipment	5 years
Leasehold improvements	Shorter of lease term or useful life

***Impairment of Long-Lived Assets***

The Company assesses the recoverability of its long-lived assets in accordance with the provisions of ASC 360, *Property, Plant and Equipment*. ASC 360 requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset or asset group. If carrying value exceeds the sum of undiscounted cash flows, the Company then determines the fair value of the underlying asset group. Any impairment to be recognized is measured by the amount by which the carrying amount of the asset group exceeds the estimated fair value of the asset group. Assets to be disposed of are reported at the lower of the carrying amount or fair value, less costs to sell. As of September 30, 2013 and December 31, 2012, the Company determined that there were no impaired assets and had no assets held-for-sale.

***Revenues******Revenue Recognition***

The Company enters into collaboration and license agreements with collaborators for the development of monoclonal antibody-based therapeutics to treat cancer and other complex diseases. The terms of these agreements contain multiple deliverables which may include (i) licenses, or options to obtain licenses, to the Company's technological platforms, such as its Fc Optimization and Dual-Affinity Re-Targeting (DART) technologies, (ii) rights to future technological improvements, (iii) research and development activities to be performed on behalf of the collaborator or as part of the collaboration, and (iv) the manufacture of pre-clinical or clinical materials for the collaborator. Payments to the Company under these agreements may include nonrefundable license fees, option fees, exercise fees, payments



for research and development activities, payments for the manufacture of pre-clinical or clinical materials, license maintenance payments, payments based upon the achievement of certain milestones and royalties on product sales. Other benefits to the Company of these agreements include the right to sell products resulting from the collaborative efforts of the parties in specific geographic territories. The Company follows the provisions of the FASB ASC Topic 605-25, *Revenue Recognition Multiple-Element Arrangements*, and ASC Topic 605-28, *Revenue Recognition Milestone Method*, in accounting for these agreements. In order to account for these agreements, the Company must

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identify the deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on the achievement of certain criteria, including whether the delivered element has stand-alone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

For the periods presented, the Company had the following two types of agreements with the parties identified below: 1) exclusive development and commercialization licenses to use the Company's technology and/or certain other intellectual property to develop compounds against specified targets (referred to herein as exclusive licenses); and 2) Option/research agreements to secure on established terms, development and commercialization licenses to anticancer and other therapeutic product candidates to collaborator selected targets developed by the Company during an option period (referred to herein as right-to-develop agreements).

There are no performance, cancellation, termination or refund provisions in any of the arrangements that contain material financial consequences to the Company.

*Exclusive Licenses*

The deliverables under an exclusive license agreement generally include the exclusive license to the Company's DART technology with respect to a specified antigen target, and may also include deliverables related to rights to future technological improvements, research and pre-clinical development activities to be performed on behalf of the collaborator. In some cases the Company may have an option to participate in the co-development of product candidates that result from such agreements.

Generally, exclusive license agreements contain nonrefundable terms for payments and, depending on the terms of the agreement, provide that the Company will (i) at the collaborator's request, provide research and pre-clinical development services at negotiated prices which are generally consistent with what other third parties would charge, (ii) earn payments upon the achievement of certain milestones, (iii) earn royalty payments, and (iv) in some cases grant the Company an option to participate in the development and commercialization of products that result from such agreements. Royalty rates may vary over the royalty term depending on the Company's intellectual property rights and whether the Company exercises any co-development and co-commercialization rights. The Company may provide technical assistance and share any technology improvements with its collaborators during the term of the collaboration agreements.

The Company does not directly control when any collaborator will achieve milestones or become liable for royalty payments.

In determining the units of accounting, management evaluates whether the exclusive license has stand-alone value from the undelivered elements to the collaborator based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research and development capabilities of the partner and the availability of technology platform and product research expertise in the general marketplace. If the Company concludes that the license has stand-alone value and therefore will be accounted for as a separate unit of accounting, the Company then determines the estimated selling prices of the license and all other units of accounting based on market conditions, similar arrangements entered into by third parties, and entity-specific factors such as the terms of the Company's previous collaboration agreements, recent pre-clinical and clinical testing results of therapeutic product candidates that use the Company's technology platforms, the Company's pricing practices and pricing objectives, the likelihood that technological improvements will be made, the likelihood that technological improvements made will be used by the Company's collaborators and the nature of the research services to be performed on behalf of its collaborators and market rates for similar services.

Upfront payments on exclusive licenses are deferred if facts and circumstances dictate that the license does not have stand-alone value. Prior to the adoption of Accounting Standards Update (ASU) No. 2009-13, *Revenue Arrangements with Multiple Deliverables*, on January 1, 2011, the Company determined that its licenses lacked stand-alone value because it did not have vendor-specific objective evidence of selling price (VSOE), and were combined with other elements of the arrangement and any amounts associated with the license were deferred and amortized over a certain period, which the Company refers to as the Company's period of substantial involvement. In making the determination of the length of the period over which to defer revenue for contracts entered into prior to the adoption of ASU No. 2009-13, significant judgment and

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estimation is used by the Company and can have an impact on the amount of revenue recognized in a given period. Historically, the Company's involvement with the development of a collaborator's product candidate has been significant at the early stages of development, and lessens as it progresses into clinical trials. Accordingly, the Company generally estimates this period of substantial involvement to begin at the inception of the collaboration agreement and conclude at the end of the Company's substantial involvement. ASU No. 2009-13 amends the criteria for separating and allocating consideration in a multiple element arrangement by modifying the fair value requirements for revenue recognition and eliminating the use of the residual value method. The selling prices of deliverables under an arrangement may be derived using third-party evidence (TPE), or a best estimate of selling price (BESP), if VSOE is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the license agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the license. In validating the BESP, management considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within the Company's control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

In determining the separate units of accounting, the Company evaluated whether the exclusive license had standalone value to the collaborator based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination included the research and development capabilities of the collaborator and the availability of relevant research expertise in the marketplace. In addition, the Company considered whether or not (i) the collaborator could use the license for its intended purpose without the receipt of the remaining deliverables, (ii) the value of the license was dependent on the undelivered items and (iii) the collaborator or other vendors could provide the undelivered items.

The Company reassesses its periods of substantial involvement over which the Company amortizes its upfront license fees and makes adjustments as appropriate. In the event a collaborator elects to discontinue development of a specific product candidate under a single target license, but retains its right to use the Company's technology to develop an alternative product candidate to the same target or a target substitute, the Company would cease amortization of any remaining portion of the upfront fee until there is substantial pre-clinical activity on another product candidate and its remaining period of substantial involvement can be estimated. In the event that a single target license were to be terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue, at the date of such termination or through the remaining substantial involvement in the wind down of the agreement.

Upfront payments on exclusive licenses may be recognized upon delivery of the license if facts and circumstances dictate that the license has stand-alone value from the undelivered elements, which generally include rights to future technological improvements, research services and the manufacture of pre-clinical and clinical materials.

The Company recognizes revenue related to research and pre-clinical development services that represent separate units of accounting as they are performed, as long as there is persuasive evidence of an arrangement, the fee is fixed or

determinable, and collection of the related receivable is probable. The Company recognizes revenue related to the rights to future technological improvements over the estimated term of the applicable license.

The Company typically performs research activities and pre-clinical development services, including generating and engineering product candidates, on behalf of its licensees during the early evaluation and pre-clinical testing stages of drug development under its exclusive licenses. The Company records amounts received for research materials produced or services performed as revenue from collaborative research.

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The Company's license agreements have milestone payments which for reporting purposes are aggregated into three categories: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the U.S. Food and Drug Administration (FDA) or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, the Company evaluates whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. The Company evaluates factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment.

Non-refundable development and regulatory milestones that are expected to be achieved as a result of the Company's efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met. Milestones that are not considered substantive because the Company does not contribute effort to the achievement of such milestones are generally achieved after the period of substantial involvement and are recognized as revenue upon achievement of the milestone, as there are no undelivered elements remaining and no continuing performance obligations, assuming all other revenue recognition criteria are met.

### *Right-to-Develop Agreements*

The Company's right-to-develop agreements provide collaborators with an exclusive option to obtain licenses to develop and commercialize in specified geographic territories product candidates developed by the Company under agreed upon research and pre-clinical development product programs. The product candidates resulting from each program are all directed to a specific target selected by the collaborator. Under these agreements, fees may be due to the Company (i) at the inception of the arrangement (referred to as upfront fees or payments), (ii) the selection of a target for a program, (iii) upon the exercise of an option to acquire a development and commercialization license (referred to as exercise fees or payments earned) for a program, or (iv) some combination of all of these fees.

The accounting for right-to-develop agreements is dependent on the nature of the options granted to the collaborator. Options are considered substantive if, at the inception of a right-to-develop agreement, the Company is at risk as to whether the collaborator will choose to exercise the options to secure development and commercialization licenses. Factors that are considered in evaluating whether options are substantive include the overall objective of the arrangement, the benefit the collaborator might obtain from the agreement without exercising the options, the cost to exercise the options relative to the total upfront consideration, and the additional financial commitments imposed on the collaborator as a result of exercising the options.

For right-to-develop agreements where the options to secure development and commercialization licenses to a product program are considered substantive, the Company does not consider the development and commercialization licenses to be a deliverable at the inception of the agreement. For those right-to-develop agreements entered into prior to the adoption of ASU No. 2009-13 where the options to secure development and commercialization licenses are

considered substantive, the Company has deferred the upfront payments received and recognizes this revenue over the period during which the collaborator could elect to exercise options for development and commercialization licenses. These periods are specific to each collaboration agreement. If a collaborator selects a target for a product program, any substantive option fee is deferred and recognized over the life of the option, generally 12 months. Subsequent to the adoption of ASU No. 2009-13, the Company's evaluation of whether the option is substantive is consistent with pre-adoption of ASU

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No. 2009-13. How the Company determines the selling price of the option is the only difference between pre and post adoption of ASU No. 2009-13. Post adoption of ASU No. 2009-13, the selling prices of deliverables under an arrangement may be derived using TPE or a BESP, if VSOE is not available. The objective of BESP is to determine the price at which the Company would transact a sale if the element within the right-to-develop agreement was sold on a standalone basis. Establishing BESP involves management's judgment and considers multiple factors, including market conditions and company-specific factors, including those factors contemplated in negotiating the agreements, as well as internally developed models that include assumptions related to market opportunity, discounted cash flows, estimated development costs, probability of success and the time needed to commercialize a product candidate pursuant to the right-to-develop agreement. In validating the BESP, management considers whether changes in key assumptions used to determine the BESP will have a significant effect on the allocation of the arrangement consideration between the multiple deliverables. Deliverables under the arrangement are separate units of accounting if (i) the delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially within the Company's control. The arrangement consideration that is fixed or determinable at the inception of the arrangement is allocated to the separate units of accounting based on their relative selling prices. The appropriate revenue recognition model is applied to each element and revenue is accordingly recognized as each element is delivered. Management exercises significant judgment in determining whether a deliverable is a separate unit of accounting.

If a collaborator exercises an option and acquires a development and commercialization license to a product program, the Company attributes the exercise fee to the development and commercialization license. The Company determines the selling price of the option license, upon exercise, through management's best estimate. Management's determination of selling price includes such factors as stage of development, market potential and cash flow models used during the negotiation with the collaborator. There have been no option license exercises to date for any period presented. Upon exercise of an option to acquire a development and commercialization license, the Company would also attribute any remaining deferred option fee to the development and commercialization license and apply the multiple-element revenue recognition criteria to the development and commercialization license and any other deliverables to determine the appropriate revenue recognition, which will be consistent with the Company's accounting policy for upfront payments on exclusive licenses even a right-to-develop agreement were to be terminated, the Company would recognize as revenue any portion of the upfront fee that had not previously been recorded as revenue, but was classified as deferred revenue, at the date of such termination. The Company's right-to-develop agreements have been determined to contain substantive options.

For right-to-develop agreements where the options to secure development and commercialization licenses to product programs are not considered substantive, the Company considers the development and commercialization licenses to be a deliverable at the inception of the agreement and applies the multiple-element revenue recognition criteria to determine the appropriate revenue recognition. The Company does not directly control when any collaborator will exercise its options for development and commercialization licenses.

***Research and Development Costs***

Research and development expenditures are expensed as incurred. Research and development costs primarily consist of employee related expenses, including salaries and benefits, expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct the Company's clinical trials, the cost of acquiring and manufacturing clinical trial materials and other allocated expenses, license fees for and milestone payments related to in-licensed products and technologies, stock-based compensation expense, and costs associated with non-clinical activities and regulatory approvals.



***Comprehensive Income (Loss)***

Effective January 1, 2012, the Company adopted ASU2011-05, *Presentation of Comprehensive Income*, which amended ASC Topic 220, *Comprehensive Income*. The amendments in ASU 2011-05 require the presentation of the comprehensive income (loss) and its components as part of the consolidated financial statements. Comprehensive income (loss) is comprised of the net income (loss) and other changes in equity that are excluded from net income (loss). Comprehensive income (loss) equals net income (loss) for the three and nine months ended September 30, 2013 and 2012.

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***Stock-based Compensation***

Stock-based payments are accounted for in accordance with the provisions of ASC 718, *Compensation – Stock Compensation*. The fair value of stock-based payments is estimated, on the date of grant, using the Black-Scholes model. The resulting fair value is recognized ratably over the requisite service period, which is generally the vesting period of the option.

For all time-vesting awards granted, expense is amortized using the straight-line attribution method. For awards that contain a performance condition, expense is amortized using the accelerated attribution method. Recognition of stock-based compensation expense is based on the value of the portion of stock-based awards that is ultimately expected to vest during the period.

The Company utilizes the Black-Scholes model for estimating fair value of its stock options granted. Option valuation models, including the Black-Scholes model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility and the expected life of the award.

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

Income (loss) per share is 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 shall declare 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 shall be 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 are participating securities.

Basic net income (loss) per common share is determined by dividing the net income (loss) allocable to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration of common stock equivalents. Diluted net income (loss) per share is computed by dividing the net income (loss) allocable 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 and the if-converted method is used to determine the dilutive effect of the Company's Series A-1, A-2, B, C, D, and D-2 convertible preferred stock.

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Basic and diluted income (loss) per common share is computed as follows:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Net income (loss)	\$ 6,603,982	\$ 2,600,514	\$ 2,944,149	\$ 10,466,582
Less: undistributed earnings allocated to participating securities	(6,434,756)	(2,600,514)	(2,944,149)	(10,466,582)
Net income (loss) allocable to common shares	\$ 169,226	\$	\$	\$
Basic weighted average common shares outstanding	1,184,507	1,092,307	1,463,798	1,078,145
<b>Basic income (loss) per common share</b>	<b>\$ 0.14</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Net income (loss)	\$ 6,603,982	\$ 2,600,514	\$ 2,944,149	\$ 10,466,582
Less: undistributed earnings allocated to participating securities and other add-backs to net income (loss)	(6,403,843)	(2,600,514)	(2,944,149)	(10,466,582)
Net income (loss) allocable to common shares	\$ 200,139	\$	\$	\$
Basic weighted average common shares outstanding	1,184,507	1,092,307	1,463,798	1,078,145
Effect of dilutive securities	20,058,471	20,410,117	20,445,061	20,334,703
Diluted weighted average common shares outstanding	21,242,978	21,502,424	21,908,859	21,412,848
<b>Diluted income (loss) per common share</b>	<b>\$ 0.01</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>

The following common stock equivalents are included in the calculation of diluted net income (loss) per share:

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Series A-1 Preferred Stock	2,156,114	2,156,114	2,156,114	2,156,114
Series A-2 Preferred Stock	392,274	392,274	392,274	392,274
Series B Preferred Stock	4,336,037	4,336,037	4,336,037	4,336,037
Series C Preferred Stock	5,909,906	5,909,906	5,909,906	5,909,906
Series D Preferred Stock	769,468	769,468	769,468	769,468
Series D-2 Preferred Stock	3,391,991	3,391,991	3,391,991	3,391,991

Warrants to purchase Series D-2				
Preferred Stock	180,784	180,784	180,784	180,784
Stock Options	2,910,952	3,276,516	2,910,952	3,276,516

***Recently Issued Accounting Standards Adopted***

In May 2011, the FASB issued ASU No. 2011-04, which amended ASC Topic 820 to achieve common fair value measurements and disclosure requirements in U.S. GAAP and International Financial Reporting Standards (IFRS). The amendments in ASU No. 2011-04 result in common fair value measurement and disclosure requirements in U.S. GAAP and IFRS. Consequently, the amendments change the wording used to describe many of the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. This amendment is effective for fiscal years beginning after December 15, 2011. The adoption of this amendment did not have a material impact on the Company's consolidated financial statements.

In June 2011, the FASB issued ASU No. 2011-05, which amended ASC Topic 220 regarding presentation of comprehensive income. The amendments in ASU No. 2011-05 require that all nonowner changes in stockholders equity be presented either in a single continuous statement of comprehensive income

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or in two separate but consecutive statements. In the two-statement approach, the first statement should present total net income and its components followed consecutively by a second statement that should present total other comprehensive income, the components of other comprehensive income, and the total of comprehensive income. This amendment is effective for fiscal years beginning after December 15, 2011. The adoption of this amendment did not have a material impact on the Company's consolidated financial statements.

The Company has evaluated all ASUs through the date the consolidated financials were issued and believes that the adoption of these will not have a material impact on the Company's consolidated financial statements.

**3. Property and Equipment**

Property and equipment consists of the following:

	<b>September 30, 2013</b>	<b>December 31, 2012</b>
Computer equipment	\$ 2,172,535	\$ 2,003,706
Software	1,323,081	1,323,081
Furniture	599,650	599,650
Lab equipment	10,603,598	8,747,790
Office equipment	51,360	51,360
Leasehold improvements	4,893,770	4,881,706
Property and equipment	19,643,994	17,607,293
Less accumulated depreciation and amortization	(15,174,112)	(14,339,497)
Property and equipment, net	\$ 4,469,882	\$ 3,267,796

Depreciation and amortization expense for the three months ended September 30, 2013 and 2012 was \$316,852 and \$235,543, respectively, and \$834,615 and \$722,496 for the nine months ended September 30, 2013 and 2012, respectively.

**4. Stockholders' Equity (Deficit)**

During 2002 and 2003, the Company issued a total of 34,239,374 shares of Series A-1 and Series A-2 convertible preferred stock (Series A preferred stock) for \$1.00 per share resulting in net proceeds of approximately \$34,000,000.

On October 12, 2004, the Company entered into a series of transactions raising \$30,261,672, net of related offering costs of approximately \$238,000, from the sale of 71,401,237 shares of its Series B convertible preferred stock (Series B preferred stock). In connection with the Series B preferred stock offering, 13,604,016 shares of common stock were allocated to holders of Series A-1 preferred stock as an anti-dilution measure but remained unissued at September 30, 2013. Upon completion of the IPO in October 2013, these allocated shares were converted into shares of common stock.

On May 16, 2006, the Company raised \$44,898,754, net of related offering costs of \$101,246, from the sale of 110,952,217 shares of its Series C convertible preferred stock (Series C preferred stock). In connection with the Series C preferred stock offering, 10,003,300 shares of common stock were allocated to holders of Series B preferred stock

as an anti-dilution measure but remained unissued at September 30, 2013. Upon completion of the IPO in October 2013, these allocated shares were converted into shares of common stock.

On July 16, 2008, the Company issued 12,466,039 shares of its Series D convertible preferred stock (Series D preferred stock) in exchange for all of the outstanding capital stock and convertible notes payable of Raven Biotechnologies, Inc. (Raven). Subsequently, in March 2011 a settlement was reached with the former Raven stockholders bringing the total Series D preferred stock issued in connection with the Raven acquisition to 14,446,227 shares.

On September 19, 2008, the Company raised \$24,843,211, net of related offering costs of \$156,788, from the sale of 38,337,678 shares of its Series D-2 convertible preferred stock (Series D-2 preferred stock). The Company also issued preferred stock warrants for the purchase of 2,875,327 shares of Series D-2 preferred

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stock. The preferred stock warrants are exercisable at any time prior to September 2018, but expire upon an IPO, and have a stated exercise price of \$0.65 per warrant. On May 16, 2010, the Company exercised a put notice to Lilly in accordance with the Series D-2 preferred stock purchase agreement, resulting in the issuance of 6,916,110 shares of Series D-2 preferred stock and a warrant to purchase 518,708 additional shares of Series D-2 preferred stock.

On January 11, 2011, the Company raised gross proceeds for \$12,016,500 from the sale of 18,427,388 shares of its Series D-2 preferred stock. Issuance costs associated with the sale were not material.

Due to certain provisions in the Series D-2 convertible preferred stock warrant agreement, these warrants are required to be classified as a liability. Management believes that the circumstances requiring cash settlement of the award are remote. The Series D-2 preferred stock warrant liability is recorded at fair value, which is adjusted at the end of each reporting period using the Option-Pricing Method, with changes in value recorded as Other income (expense) in the accompanying consolidated statements of operations.

Holders of the Series A-1, Series A-2, Series B, Series C, Series D and Series D-2 preferred stock are entitled to vote, together with the common stockholders as one class, on all matters as to which common stockholders are entitled to vote. In any such vote, each share of Series A, Series B, Series C and Series D preferred stock shall entitle the holder to the number of votes per share that equals the number of shares of common stock into which each such share of preferred stock is then convertible. For so long as at least four million shares of each of the Series A, Series B and Series C preferred stock remain outstanding, the holders of each of the Series A, Series B and Series C preferred stock, each voting as a separate class, shall each be entitled to elect two members of the Board of Directors of the Company. The holders of a majority of the common stock, voting as a separate class, shall have the right to elect one member of the Board of Directors of the Company. The holders of a majority of the common stock and the holders of at least 66 2/3% of the preferred stock, each voting separately as a single class (and on an as-if-converted basis to common stock with respect to the preferred stock), shall be entitled to elect all remaining members of the Board of Directors.

Dividends are noncumulative and accrue on the Series A-1, Series A-2, Series B, Series C, Series D and Series D-2 preferred stock at a rate of \$0.08, \$0.0341, \$0.0324 and \$0.0522 per annum, respectively, and are payable when and as declared by the Board of Directors. Dividends must be declared so that the Series A, Series B, Series C and Series D preferred stock are paid in like-kind and participate equally to those of the Series D-2 preferred and common stock. No dividends have been declared and none are accrued at September 30, 2013 or December 31, 2012.

The Company's Series A-1, Series A-2, Series B, Series C, Series D and Series D-2 preferred stock are initially convertible into 1.506, 1.00, 1.14, 1.00, 1.00 and 1.00 shares, respectively, of common stock at the option of the holder. The conversion ratio of certain series of preferred stock is subject to change in the event specified dilutive transactions occur. These dilutive events are considered to be the sale of common stock at a per share price less than the applicable preferred stock conversion price. There are no anti-dilution protections for the Series A-2 preferred stock and no adjustment to the Series A-1 preferred stock conversion price is made if a common stock issuance is at a price per share greater than the conversion price of the Series C preferred stock. The conversion price shall be \$12.39, \$18.77, \$6.95, \$7.70, \$12.20 and \$12.20 for each share of Series A-1, A-2, Series B, Series C, Series D and Series D-2 convertible preferred stock, respectively. The Company has reserved 17,129,782 shares of common stock for the potential conversion of the Series A-1, Series A-2, Series B, Series C, Series D and Series D-2 preferred stock.

Each share of Series A-1, Series A-2, Series B, Series C, Series D and Series D-2 preferred stock automatically converts into shares of the Company's common stock upon closing of a firm commitment underwritten public offering of common stock registered under the Securities Act of 1933 which generates net proceeds to the Company of at least \$40 million. The holders of two-thirds of the Series A-1, Series A-2, Series B, Series C, Series D and Series D-2

preferred stock, voting together as a single class, but separately from the common stockholders, shall have the right to elect to convert all outstanding shares of Series A-1, Series A-2, Series B, Series C, Series D and Series D-2 preferred stock into shares of common stock.

In liquidation, the holders of Series D-2 preferred stock are entitled to receive \$12.20 per share prior to any distribution to the holders of any Series C and Series D preferred stock. The holders of Series C and Series D preferred stock are entitled to receive \$7.70 and \$12.20 per share, respectively, on a *pari passu* basis,



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prior to any distribution to the holders of any Series B preferred stock. The holders of Series B preferred stock are entitled to receive \$6.95 per share prior to any distribution to the holders of any shares of Series A preferred stock. The holders of Series A preferred stock are entitled to receive \$12.39 per share prior to the holders of common stock.

In connection with preparing for its IPO in October 2013 (see Note 11, Subsequent Events, for additional information), the Company's Board of Directors and stockholders approved a 1-for-18.7739 reverse stock split of the Company's Common Stock. The reverse stock split became effective on September 26, 2013. All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital. In addition, in September 2013, the Company's Board of Directors and stockholders approved an amendment of the Company's certificate of incorporation to, among other things, change the definition of a designated public offering to remove the per share price requirement.

**5. Shared-Based Payments*****Stock Option Plan***

The Company's 2000 Stock Option and Incentive Plan (the 2000 Plan) allowed for the grant of awards in respect of an aggregate of 130,725 shares, which was increased to 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.

Effective February 2003, the Company implemented the 2003 Equity Incentive Plan (the 2003 Plan), and it was amended and approved by the Company's stockholders in 2005. The 2003 Plan originally allowed for the grant of awards in respect of an aggregate of 2,051,644 shares of the Company's common stock. During the year ended December 31, 2006, the maximum number of shares of common stock authorized to be issued by the Company under the 2003 Plan was increased by 460,746 shares to 2,512,390. During the year ended December 31, 2008, the maximum number of shares of common stock authorized to be issued by the Company under the 2003 Plan was increased by 745,716 shares to 3,258,106. During the year ended December 31, 2010, the maximum number of shares of common stock authorized to be issued by the Company under the 2003 Plan was increased by 532,654 shares to 3,790,760. During the year ended December 31, 2012, the maximum number of shares of common stock authorized to be issued by the Company under the 2003 Plan was increased by 545,970 shares to 4,336,731. As of September 30, 2013, a total of 8,171 shares were available for issuance under the 2003 Plan.

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.

The following stock-based compensation amounts were recognized for the periods indicated:

	<b>Three Months Ended September 30,</b>		<b>Three Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>	<b>2013</b>	<b>2012</b>
Research and development	\$ 111,888	\$ 117,952	\$ 284,281	\$ 353,856
General and administrative	24,048	91,647	109,280	274,940
<b>Total stock-based compensation expense</b>	<b>\$ 135,936</b>	<b>\$ 209,599</b>	<b>\$ 393,561</b>	<b>\$ 628,796</b>



**Table of Contents***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:

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
Expected dividend yield	0%	0%
Expected volatility	53% - 58%	51%
Risk-free interest rate	1.24% - 2.05%	1.18%
Expected average life of options	7 years	7 years
Fair market value of common stock at:	\$1.50 - \$7.51	\$1.50
Expected forfeiture rate	5.06%	5.57%

**Fair Value of Common Stock** Before our entry into the public market on October 10, 2013, the Company's Board of Directors determined the fair value of the common stock. The Board of Directors made determinations of fair value based, in part, upon contemporaneous valuations to determine fair value. In the absence of a public market, and as a clinical-stage company with no significant revenues, the Company believes that it is appropriate to consider a range of factors to determine the fair market value of the common stock at each grant date. The factors include: (1) the achievement of clinical and operational milestones by the Company; (2) the status of strategic relationships with collaborators; (3) the significant risks associated with the Company's stage of development; (4) capital market conditions for life science companies, particularly similarly situated, privately held, early-stage life science companies; (5) the Company's available cash, financial condition and results of operations; (6) the most recent sales of the Company's preferred stock and (7) the preferential rights of the outstanding preferred stock. The contemporaneous valuations were performed in accordance with applicable methodologies, approaches and assumptions of the technical practice-aid issued by the American Institute of Certified Public Accountants Practice Aid entitled *Valuation of Privately-Held Company Equity Securities Issued as Compensation*.

**Expected Volatility** Volatility is a measure of the amount by which a financial variable such as a share price has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. The Company does not maintain an internal market for its shares and its shares are not traded publicly. The Company has been able to identify several public entities of similar size, complexity and stage of development; accordingly, historical volatility has been calculated using the volatility of these companies.

**Expected Dividend Yield** The Company has never declared or paid dividends and has no plans to do so in the foreseeable future.

**Risk-Free Interest Rate** This is the U.S. Treasury rate for the week of each option grant during the year, having a term that most closely resembles the expected life of the option.

**Expected Term** This is the period of time that the options granted are expected to remain unexercised. Options granted have a maximum term of ten years. The Company estimates the expected life of the option term to be seven years. The Company uses a simplified method to calculate the average expected term.

**Expected Forfeiture Rate** The forfeiture rate is the estimated percentage of options granted that is expected to be forfeited or canceled on an annual basis before becoming fully vested. The Company estimates the forfeiture rate based on turnover data with further consideration given to the class of the employees to whom the options were

granted.

Equity instruments issued to non-employees are accounted for under the provisions of ASC 505-50, *Equity Based Payments to Non-Employees*. Accordingly, the estimated fair value of the equity instrument is recorded on the earlier of the performance commitment date or the date the services required are completed.

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The following table summarizes stock option activity under the Plan during the period then ended:

	<b>Number of Options</b>	<b>Weighted- Average Exercise Price</b>	<b>Weighted- Average Contractual Term (in Years)</b>
Outstanding, December 31, 2012	3,249,702	0.94	7.3
Granted	687,183	3.19	7.0
Exercised	(1,025,933)	0.75	
Forfeited or expired	(33,949)	1.13	
Outstanding, September 30, 2013	2,877,003	1.50	7.2
September 30, 2013:			
Exercisable	1,855,178	0.94	
Vested and Expected to Vest	918,600	2.44	

The aggregate intrinsic value of options outstanding and options exercisable as of September 30, 2013 is approximately \$17.4 million and \$12.2 million, respectively.

The weighted-average grant-date fair value of options granted for the nine months ended September 30, 2013 was \$2.00. Total cash received for the options exercised was \$851,183 for the nine months ended September 30, 2013. The total fair value of shares vested in the nine months ended September 30, 2013 was \$402,084. As of September 30, 2013, the total unrecognized compensation expense related to non-vested stock-based compensation arrangements granted under the 2000 Plan and 2003 Plan, net of related forfeiture estimates, was \$1.5 million, which the Company expects to recognize over a weighted-average period of approximately four years.

**6. 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*. In connection with the acquisition, the Company issued 12,466,039 shares of its Series D convertible preferred stock in exchange for all of the outstanding capital stock and convertible notes payable of Raven.

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 completed 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.

Changes in the lease exit liability are as follows:

Accrual balance at December 31, 2011	\$ 10,607,499
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Principal payments	(533,560)
Accrual balance at December 31, 2012	10,073,939
Principal payments	(466,301)
Accrual balance at September 30, 2013	\$ 9,607,638

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Future principal payments to be made under the lease agreement for the next five years and thereafter as of September 30, 2013 are as follows:

Twelve Months Ending September 30,	
2014	\$ 1,229,454
2015	1,589,410
2016	1,808,119
2017	2,049,273
2018	2,315,026
Thereafter	616,356
	\$ 9,607,638

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.

The contingent consideration will be accounted for as additional purchase price and recorded as incremental in-process research and development expense when it is deemed probable that the contingencies will be attained. No additional amounts have been recorded during the nine months ended September 30, 2013 and 2012.

## **7. Collaboration and License Agreements**

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

In November 2011, the Company entered into a right-to-develop collaboration agreement with 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 nonrefundable payment of \$20 million to the Company. The Company is eligible to receive up to \$30 million in license grant fees, \$47 million in clinical milestone payments, \$140 million in regulatory milestone payments and \$208 million in sales milestone payments if Servier exercises the option, obtains regulatory approval for and successfully commercializes MGA271. The Company concluded that the license grant 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 grant 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 fees 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 during the first year of the agreement and participation on an executive committee and a research



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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 is being recognized ratably over the initial 27-month period, which represents the expected period of development and the Company's participation on the research and development committee. The Company further concluded that each potential future clinical, development and regulatory milestone is substantive.

During the three months ended September 30, 2013 and 2012 the Company recognized revenue of \$12.3 million (including a \$10.0 million milestone payment) and \$2.3 million, respectively. During the nine months ended September 30, 2013 and 2012 the Company recognized revenue of \$18.9 million (including a \$10.0 million milestone payment) and \$6.8 million, respectively, under this agreement.

At September 30, 2013, \$3.1 million of revenue was deferred under this agreement, all of which was included in current liabilities. At December 31, 2012, \$10.0 million of revenue was deferred under this agreement, \$9.1 million of which was included in current liabilities and \$0.9 million was included in long-term liabilities.

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-based 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.

Upon execution of the agreement, Servier made a nonrefundable payment of \$20 million to the Company. In addition, the Company will be eligible to receive up to \$65 million in license grant fees, \$98 million in clinical milestone payments, including \$5 million upon IND acceptance for each of MGD006, MGD007 and a third DART molecule, \$300 million in regulatory milestone payments and \$630 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, 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 during the first year of the agreement 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 up front license payment was deferred and is being recognized ratably over the initial 29-month period, which represents the expected development period. The Company further concluded that each potential future clinical, development and regulatory milestone is substantive.

During the three and nine months ended September 30, 2013 the Company recognized revenue of \$2.2 million and \$6.5 million, respectively. No revenue was recognized under this agreement during the comparable periods in 2012.

No milestones have been recognized under this agreement during the three and nine months ended September 30, 2013.

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At September 30, 2013, \$11.6 million of revenue was deferred under this agreement, \$8.6 million of which was included in current liabilities and \$3.0 million of which was included in long-term liabilities. At December 31, 2012, \$18.0 million of revenue was deferred under this agreement, \$8.6 million of which was included in current liabilities and \$9.4 million of which was included in long-term liabilities.

### ***Gilead Sciences, Inc.***

In January 2013, the Company entered into an agreement with Gilead to grant it an exclusive worldwide license to research, develop and commercialize up to four DART-based molecules. Gilead has exclusive worldwide rights for three of the programs. For one program, the Company retains development and commercialization rights outside of North America, the European Union, Norway, Iceland, Turkey, Australia and New Zealand.

The Company received an initial \$7.5 million license grant fee for the first DART-based molecule. The Company may be eligible to receive additional license grant fees of \$22.5 million, \$200 million related to pre-clinical and clinical milestones, \$355 million related to regulatory milestones and \$500 million related to sales milestones if Gilead exercises all four of the options and successfully develops, obtains regulatory approval for, and commercializes a product under each option and license. The Company has determined that the other 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, but less than teen royalties on product sales in its territories.

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.

Receivables of \$1.1 million as of September 30, 2013 relate to amounts due to the Company from Gilead for reimbursement work performed under the collaboration.

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

At September 30, 2013, \$4.4 million of revenue was deferred under this agreement, all of which was included in current liabilities.

***Boehringer Ingelheim International GmbH***

In October 2010 the Company entered into a collaboration and license agreement with Boehringer to discover, develop and commercialize up to ten DART-based 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, or the Boehringer licensed products, throughout the world.

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Upon execution of the agreement, the Company received an upfront payment of \$15 million. The Company subsequently received two annual maintenance payments and anticipates receiving a third annual maintenance payment in the fourth quarter of 2013. The first two maintenance payments were solely attributed to the passage time. Because Boehringer has the option to cancel the program after the second anniversary of the agreement, the third maintenance payment will be recognized over the remaining obligation period once received. The Company has the potential to earn milestone payments of approximately \$41 million related to pre-clinical and clinical development, \$89 million related to regulatory milestones and \$83 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. From the commencement of the collaboration through September 30, 2013, the Company has received \$39.0 million under this agreement, including upfront, annual maintenance and milestone payments as well as research funding. In addition, Boehringer purchased \$10 million of the Company's Series D-2 Preferred Stock in January 2011.

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 account 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 organization period for the research and development services.

There have been no material modifications to this agreement since the adoption of ASU 2009-13 on January 1, 2011.

Receivables of \$246,375 and \$355,568 as of September 30, 2013 and December 31, 2012, respectively, relate to amounts due to the Company from Boehringer for reimbursement work performed under the collaboration.

The Company recognized revenues of approximately \$2.3 million and \$2.5 million under this agreement during the three months ended September 30, 2013 and 2012, respectively, and \$6.9 million and \$9.3 million during the nine months ended September 30, 2013 and 2012, respectively. One milestone payment of \$2.0 million was recognized under this agreement through December 2012. No milestones have been recognized under this agreement during the three and nine months ended September 30, 2013. A milestone was earned under this agreement subsequent to September 30, 2013. See Note 11, Subsequent Events, for additional information.

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At September 30, 2013, \$10.3 million of revenue was deferred under this agreement, \$5.0 million of which was included in current liabilities and \$5.3 million of which was included in long-term liabilities. At December 31, 2012, \$14.0 million of revenue was deferred under this agreement, \$5.0 million of which was included in current liabilities and \$9.0 million of which was included in long-term liabilities.

***Pfizer, Inc.***

In October 2010, the Company entered into a three year agreement with Pfizer to discover, develop and commercialize up to two DART-based molecules. The Company granted Pfizer a non-exclusive worldwide, royalty-bearing license and received an upfront payment of \$5 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 million related to pre-clinical and clinical development and \$195 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-teen royalties on product sales. Under this collaboration, one DART program is currently being pursued and the Company will complete 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 represents the estimated period of development.

The \$5 million upfront payment received by the Company is non-refundable; therefore, there is no right of return for the license. The Company is recognizing revenue associated with this non-refundable up-front license fee through 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.

There have been no material modifications to this agreement since the adoption of ASU 2009-13 on January 1, 2011.



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Receivables of \$501,794 and \$896,285 as of September 30, 2013 and December 31, 2012, respectively, relate to amounts due to the Company from Pfizer for reimbursement work performed under the collaboration.

The Company recognized revenues of approximately \$0.9 million and \$1.2 million under this agreement during the three months ended September 30, 2013 and 2012, respectively, and \$3.2 million and \$4.0 million during the nine months ended September 30, 2013 and 2012, respectively. Included in the 2012 revenues are milestone payments totaling \$500,000. No additional milestones have been recognized under this agreement through September 30, 2013.

At September 30, 2013 and December 31, 2012, \$58,000 and \$1.3 million of revenue was deferred under this agreement, all of which was included in current liabilities.

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

In June 2010, the Company entered into a collaboration agreement with Green Cross for the development of the Company's anti-HER2 antibody known as MGAH22, or 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.

Upon execution of the agreement, Green Cross made a nonrefundable payment of \$1.0 million to the Company. The Company is eligible to receive clinical development and commercial milestone payments of up to \$4.5 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. The Company's substantive performance obligations under this agreement include an exclusive license to its technologies and participation in a joint steering committee. The Company concluded that the license does not have value on a standalone basis and therefore does not represent a separate unit of accounting. Likewise, Green Cross could not sell the license to another party.

The \$1 million upfront payment received by the Company 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.

There have been no material modifications to this agreement since the adoption of ASU 2009-13 on January 1, 2011.

The Company recognized revenues of approximately \$25,000 under this agreement during each of the three month periods ending September 30, 2013 and 2012, and \$75,000 during each of the nine month periods ending September 30, 2013 and 2012. No milestones have been recognized under this agreement during the three and nine months ended September 30, 2013.

At September 30, 2013, \$675,000 of revenue was deferred under this agreement, \$100,000 of which was included in current liabilities and \$575,000 of which was included in long-term liabilities. At December 31, 2012, \$750,000 of revenue was deferred under this agreement, \$100,000 of which was included in current liabilities and \$650,000 of which was included in long-term liabilities.

### ***Eli Lilly & Co.***

In October 2007, the Company entered into an exclusive license and collaboration agreement (together, the Agreements) with Eli Lilly to jointly develop and commercialize teplizumab, a humanized anti-CD3 monoclonal antibody. As part of the Agreements, Eli Lilly acquired the exclusive rights to the molecule.

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Upon execution of the Agreements, Eli Lilly made a nonrefundable payment of \$41.0 million to the Company. In May 2008, Eli Lilly paid the Company a milestone payment of \$50.0 million and in May 2010, Eli Lilly paid an additional milestone of \$5.0 million.

On October 28, 2010, Lilly notified the Company of its decision to terminate the agreement after review of one year of clinical data from the PROTÉGÉ trial in Type 1 diabetes patients treated with teplizumab. Such data failed to support the primary efficacy end point in the study. During the year ended December 31, 2012, Eli Lilly satisfied its obligation related to the cost of monitoring patients under the PROTÉGÉ and ENCORE trials. The Company's obligations continued through September 2012, which represented the follow up period for enrolled patients and the Company's final reporting of the trial's results. There is no additional clinical trial activity under the Eli Lilly Agreements as it relates to such trials. In February 2011, the Company reacquired the commercial rights to the molecule from Eli Lilly.

Receivables of \$244,542 and \$558,516 as of September 30, 2013 and December 31, 2012, respectively, relate to amounts due to the Company from Eli Lilly for reimbursement work performed under the above mentioned clinical trials.

During the three months ended September 30, 2013 and 2012, the Company recognized revenue of \$190,833 and \$9.5 million, respectively, under this agreement. During the nine months ended September 30, 2013 and 2012, the Company recognized revenue of \$673,927 and \$30.1 million, respectively. No milestones were recognized under this agreement during the three and nine months ended September 30, 2013.

**8. Commitments and Contingencies*****Operating Leases***

The Company leases office and laboratory space over periods extending through January 30, 2018. Several of the leases contain rent escalation clauses. Rent expense for the three months ended September 30, 2013 and 2012 was \$806,275 and \$783,462, respectively. The Company incurred \$2.4 million of rent expense for each of the nine-month periods ending September 30, 2013 and 2012.

Future minimum lease payments under noncancelable operating leases at September 30, 2013 are as follows:

Twelve Months Ending September 30,	
2014	\$ 3,460,609
2015	3,396,780
2016	3,385,321
2017	3,486,881
2018	3,035,013
Thereafter	625,540
	\$ 17,390,144

**9. Product Milestone Payments and Royalty Agreements**

In connection with an Asset Purchase Agreement with Tolerance Therapeutics, Inc. (Tolerance) entered into during June 2005, the Company may be required to issue Tolerance additional consideration as follows: (i) \$10,950,000 if certain milestones are met, including the initiation of Phase 3 trials and filing of various regulatory product license applications; (ii) 36,135 shares of common stock; and (iii) royalty payments between 1.75% and 4.0% of net sales of products acquired from or patented by Tolerance or other product fees earned by the Company. Any additional consideration required to be paid under the Asset Purchase Agreement will be recorded as research and development expense when incurred. No payments related to the additional consideration have occurred during the three and nine-month periods ended September 30, 2013 or 2012. Additionally, certain agreements require the Company to pay royalties. Currently, the Company is not obligated to pay royalties, as no other revenue from product sales is being generated by the Company.

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**10. Employee Benefit Plan**

On September 25, 2002, the Company established the MacroGenics 401(k) Plan (the Plan) for its employees under Section 401(k) of the IRC. Under this Plan, all employees at least 21 years of age are eligible to participate in the Plan, starting on the first day of each month. Employees may contribute up to 100% of their salary, subject to government maximums.

Employees are 100% vested in their contributions to the Plan. The Company's contribution to the Plan, as determined by the Board of Directors, is discretionary. The Company's contributions to the Plan totaled \$55,311 and \$48,891 for the three months ended September 30, 2013 and 2012, respectively, and \$194,498 and \$179,966 for the nine months ended September 30, 2013 and 2012, respectively.

**11. Subsequent Events**

On October 16, 2013, the Company completed its IPO, in which 5,000,000 shares of the Company's common stock were sold at a price of \$16 per share. Additionally, the underwriters of the Company's IPO exercised the full amount of their over-allotment option resulting in the sale of an additional 750,000 shares of the Company's common stock at a price of \$16 per share. The Company received net proceeds of \$83.8 million from the IPO, net of underwriting discounts and commissions and other estimated offering expenses. Upon consummation of the IPO, all outstanding shares of preferred stock automatically converted to common stock at the applicable conversion ratios then in effect. Subsequent to the IPO, the Company had 25,020,288 issued and outstanding shares of common stock and no outstanding shares of preferred stock.

In November 2013, Boehringer nominated a bi-specific antibody therapeutic candidate generated by the Company's DART technology for pre-clinical development. This formal selection of a development candidate triggered a \$5.0 million milestone payment to the Company under the October 2010 agreement described in Note 7, Collaboration and License Agreements. In addition, Boehringer will pay a research maintenance payment of \$4.0 million to the Company in the fourth quarter of 2013.

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**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 Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, with the Securities and Exchange Commission, on October 11, 2013 (Prospectus). This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under the section entitled "Risk Factors" and elsewhere in this report, our actual results may differ materially from those anticipated in these forward-looking statements.*

**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.

We currently have two oncology product candidates in clinical development. Additionally, we have several proprietary product candidates in pre-clinical development and we expect to commence Phase 1 clinical trials on two of these product candidates in 2014.

*Margetuximab*, also known as MGAH22, 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 currently are enrolling a Phase 2a clinical trial in metastatic breast cancer and anticipate commencing a Phase 3 potential registration clinical trial in advanced gastroesophageal cancer in the second half of 2014.

*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 have initiated a Phase 1 clinical trial that we expect to complete by the end of 2014.

*MGD006* is a humanized DART molecule that recognizes CD123, the Interleukin-3 receptor, or IL3R, alpha chain which is expressed on leukemia and leukemic stem cells, but not on normal hematopoietic stem cells,

and CD3, which is expressed on T cells. We expect to commence a Phase 1 clinical trial in the first half of 2014.

*MGD007* is a humanized DART molecule that recognizes both the glycoprotein A33, expressed on gastrointestinal tumors, including more than 95% of human colon cancers, and CD3, which is expressed on T cells. We expect to commence a Phase 1 clinical trial in the second half of 2014.

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 our convertible preferred stock, collaborations and government grants and

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contracts. From inception through September 30, 2013, we have received \$151.3 million from the sale of convertible preferred stock and warrants. We have received an additional \$190.0 million of upfront, milestone and annual maintenance payments from our collaborators and have been reimbursed \$219.4 million through our collaborations and government grants and contracts. As described more fully in Note 11 to the financial statements, 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. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we anticipate that the net proceeds from the IPO, together with our existing cash and cash equivalents, and a significant portion of the \$100 million in collaboration payments we anticipate receiving through 2015, will enable us to fund the clinical development of margetuximab, MGA271, MGD006, MGD007 and MGD010 through 2015, assuming all of our collaboration programs advance as currently contemplated.

Through September 30, 2013, we had an accumulated deficit of \$172.0 million. Due primarily to upfront fees paid by our collaborators, we realized a profit of \$6.6 million and \$2.9 million for the three and nine months ended September 30, 2013, respectively. 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.

*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 have received a \$20 million option grant fee and a \$10 million milestone payment, and may be eligible to receive up to approximately \$415 million in license grant fees, and clinical, development, regulatory and sales milestone payments. In the event Servier exercises its option, Servier must pay a license grant fee, which we estimate to be \$30 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-based 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 million option grant fee. In addition, we will be eligible to receive up to approximately \$1 billion in additional license grant 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 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.

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



*Gilead.* In January 2013, we entered into an agreement with Gilead to grant it an exclusive worldwide license to research, develop and commercialize up to four DART-based molecules. Gilead has exclusive worldwide rights for three of the programs. For one program, we retain development and commercialization rights outside of North America, the European Union, Norway, Iceland, Turkey, Australia and New Zealand. We received an initial \$7.5 million license grant fee for the first DART-based molecule, and are eligible to receive up to an additional \$22.5 million in grant fees on the remaining three DART-based molecules. We are

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further eligible to receive up to an additional \$85 million in pre-clinical milestones across the four DART programs and up to approximately \$1 billion in additional clinical, regulatory and sales milestone payments if Gilead exercises all four of the options and achieves all of the requisite milestones under each option and license. Gilead also provides funding for our internal and external research costs under the agreement. We are also eligible to receive tiered royalties on the net sales at percentages ranging from the high-single digits to the low double digits, but less than teens, subject to reductions in specified circumstances.

*Boehringer.* In October 2010, we entered into an agreement with Boehringer to discover, develop and commercialize up to ten DART-based molecules which may span multiple therapeutic areas. We granted Boehringer an exclusive worldwide, royalty-bearing, license and received an upfront payment of \$15 million. We subsequently received two annual maintenance payments and anticipate receiving a third annual maintenance payment in the fourth quarter of 2013. We have the potential to earn development, regulatory and sales milestone payments that can reach up to approximately \$210 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. From the commencement of the collaboration through September 30, 2013, we have received \$37.9 million under this agreement, including upfront, annual maintenance and milestone payments as well as research funding. In addition, Boehringer purchased \$10 million of our Series D-2 Preferred Stock in January 2011. Subsequent to September 30, 2013, Boehringer nominated a bi-specific antibody therapeutic candidate generated by our DART technology for pre-clinical development. This formal selection of a development candidate triggered a \$5.0 million milestone payment to us under the agreement. In addition, Boehringer will pay a research maintenance payment of \$4.0 million.

*Pfizer.* In October 2010, we entered into a three year agreement with Pfizer to discover, develop and commercialize up to two DART-based molecules. We granted Pfizer a non-exclusive worldwide, royalty-bearing license and received an upfront payment of \$5 million and have received milestone payments and funding for our internal and external research costs under the agreement. We are eligible to receive technical, development and sales milestone payments that can reach up to approximately \$210 million for each DART program under this agreement. Pfizer is responsible for all pre-clinical and clinical development costs for the program. In addition, Pfizer is required to pay us mid-single digit to low-teen royalties on product sales. Under this collaboration, one DART program is currently being pursued and we will complete our research obligations under this program in January 2014.

*Green Cross.* In June 2010, we entered into a collaboration agreement with Green Cross for the development of margetuximab. We granted Green Cross an exclusive license for all indications for all pharmaceutical forms of margetuximab in South Korea. Under the terms of this agreement, we received an upfront, nonrefundable payment of \$1.0 million and are eligible to receive clinical, development and commercial milestone payments up to \$4.5 million as well as royalties ranging from the low-single digits to the low-twenties on net sales of margetuximab in South Korea. In addition, Green Cross purchased \$2.0 million of our Series D-2 Preferred Stock in January 2011.

**Financial Operations Overview*****Revenues***

Our revenue consists of collaboration revenue, including amounts recognized relating to upfront nonrefundable payments for licenses or options to obtain future licenses, research and development funding and milestone payments earned under our collaboration and license agreement with our strategic collaborators, including Servier, Gilead, Boehringer, Pfizer and Green Cross. In addition, we have earned revenues through several grants and/or contracts with the U.S. government and other educational institutions on behalf of the U.S. government, primarily with respect to research and development activities related to infectious disease product candidates.

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***Research and Development Expense***

Research and development expenses consist of expenses incurred in performing research and development activities. These expenses include conducting pre-clinical experiments and studies, clinical trials, manufacturing efforts and regulatory filings for all product candidates, and other indirect expenses in support of our research and development activities. We capture research and development expense on a program-by-program basis for our product candidates that are in clinical development and recognize these expenses as they are incurred. The following are items we include in research and development expenses:

Employee-related expenses such as salaries and benefits;

Employee-related overhead expenses such as facilities and other allocated items;

Stock-based compensation expense to employees and consultants engaged in research and development activities;

Depreciation of laboratory equipment, computers and leasehold improvements;

Fees paid to consultants, subcontractors, clinical research organizations (CROs) and other third party vendors for work performed under our pre-clinical and clinical trials including but not limited to investigator grants, laboratory work and analysis, database management, statistical analysis, and other items;

Amounts paid to vendors and suppliers for laboratory supplies;

Costs related to manufacturing clinical trial materials, including vialing, packaging and testing;

License fees and other third party vendor payments related to in-licensed product candidates and technology; and

Costs related to compliance with regulatory requirements.

It is difficult to determine with certainty the duration and completion costs of our current or future pre-clinical programs and clinical trials of our product candidates, or if, when or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates. The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors, including the uncertainties of future clinical trials and pre-clinical studies, uncertainties in clinical trial enrollment rate and significant and changing government regulation. In addition, the probability of success for each product candidate will depend on numerous factors, including competition, manufacturing capability and commercial viability. We will determine which programs

to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

***General and Administrative Expense***

General and administrative expenses consist of salaries and related benefit costs for employees in our executive, finance, legal and intellectual property, business development, human resources and other support functions, travel expenses and other legal and professional fees.

***Other Income (Expense)***

Other income (expense) consists of interest income earned on our cash equivalents, offset by interest expense and other expense, including changes in the fair market value of the preferred stock warrant liability.

**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. Management has determined that our most critical accounting policies are those relating to revenue recognition and stock-based compensation. There have been no significant changes to our critical accounting policies discussed in the Prospectus.

**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, 2013 and 2012:

	<b>Three Months Ended September 30,</b>		<b>Increase/(Decrease)</b>	
	<b>2013</b>	<b>2012</b>		
	<b>(dollars in millions)</b>			
Revenue from collaborative research	\$ 20.1	\$ 15.5	\$ 4.6	30%
Grant revenue	0.1	0.5	(0.4)	(80%)
<b>Total revenue</b>	<b>\$ 20.2</b>	<b>\$ 16.0</b>	<b>\$ 4.2</b>	<b>26%</b>

	<b>Nine Months</b>		<b>Increase/(Decrease)</b>	
	<b>Ended September 30,</b>	<b>2012</b>		
	<b>2013</b>	<b>2012</b>		
	<b>(dollars in millions)</b>			
Revenue from collaborative research	\$ 42.0	\$ 50.3	\$ (8.3)	(17%)
Grant revenue	1.1	3.7	(2.6)	(70%)
<b>Total revenue</b>	<b>\$ 43.1</b>	<b>\$ 54.0</b>	<b>\$ (10.9)</b>	<b>(20)%</b>

The increase in collaboration revenue of \$4.6 million for the three months ended September 30, 2013 compared to the same period in 2012 is due to the receipt of a \$10.0 million milestone payment under our agreement with Servier and the addition of our collaboration with Gilead. These increases are partially offset by a decrease in teplizumab clinical trial-related reimbursement revenue from our former collaborator, Eli Lilly.

The decrease in collaboration revenue of \$8.3 million for the nine months ended September 30, 2013 compared to the same period in 2012 is primarily due to the conclusion of the teplizumab clinical trial-related reimbursement from Eli Lilly. Aside from reimbursing us for the continued monitoring expense of one on-going trial, Eli Lilly's participation in the development of teplizumab concluded in the first quarter of 2013.

Grant revenue decreased in the three and nine month periods ended September 30, 2013 as compared to the same periods in 2012 due primarily to the completion of grants to study H5N1 influenza virus, small pox and West Nile virus.

**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, 2013 and 2012:

	Three Months Ended September 30, Increase/(Decrease)			
	2013	2012		
	(dollars in millions)			
Margetuximab	\$ 1.3	\$ 1.4	\$ (0.1)	(7%)
MGA271	1.2	2.1	(0.9)	(43%)
DART-based product candidates	6.6	3.1	3.5	113%
Teplizumab	0.7	3.9	(3.2)	(82%)
Other discovery and pre-clinical programs, collectively	1.3	1.5	(0.2)	(13%)
<b>Total research and development expense</b>	<b>\$ 11.1</b>	<b>\$ 12.0</b>	<b>\$ (0.9)</b>	<b>(8%)</b>

	Nine Months Ended September 30, 20132012 (dollars in millions)		Increase/(Decrease)	
Margetuximab	\$ 4.4	\$ 4.4	\$	0%
MGA271	4.8	4.5	0.3	7%
DART-based product candidates	17.2	8.2	9.0	110%
Teplizumab	1.9	13.3	(11.4)	(86%)
Other discovery and pre-clinical programs, collectively	3.9	6.5	(2.6)	(40%)
<b>Total research and development expense</b>	<b>\$ 32.2</b>	<b>\$ 36.9</b>	<b>\$ (4.7)</b>	<b>(13%)</b>

During the three months ended September 30, 2013 our research and development expense decreased by \$0.9 million compared to the same period in 2012 due to the reduction in spending on teplizumab related clinical development, offset by an increase in spending on DART-based product candidates. During the nine months ended September 30, 2013, as compared to the same period in 2012, our research and development expense decreased by \$4.7 million. This decrease was due primarily to the reduction in spending on teplizumab-related clinical development as we ended trial enrollment and began closing down the trials during this period. In addition, we significantly reduced our Cancer Stem-like Cell (CSLC) related activities. These decreases were partially offset by an increase in spending on MGA271 and our various DART-based product candidates.

**Table of Contents*****General and Administrative Expense***

The following represents a comparison of our general and administrative expense for the three and nine months ended September 30, 2013 and 2012:

	Three Months Ended September 30, Increase/(Decrease)			
	2013	2012		
	(dollars in millions)			
General and administrative expense	\$ 2.0	\$ 1.5	\$ 0.5	32%

	Nine Months Ended September 30,		Increase/(Decrease)	
	2013	2012		
	(dollars in millions)			
General and administrative expense	\$ 7.3	\$ 6.6	\$ 0.7	11%

General and administrative expense increased for the three and nine months ended September 30, 2013 by \$0.5 million and \$0.7 million, respectively, compared to the same period in 2012 primarily due to an increase in professional fees and other costs associated with preparations for public company operations, including extensive studies performed for potential tax and other credits.

***Cash Flows***

The following table represents a summary of our cash flows for the nine months ended September 30, 2013 and 2012:

	<b>Nine Months Ended September 30,</b>	
	<b>2013</b>	<b>2012</b>
	<b>(dollars in millions)</b>	
<b>Net cash provided by (used in):</b>		
Operating activities	\$ (13.0)	\$ (24.3)
Investing activities	(2.0)	(0.5)
Financing activities	0.9	0.0
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>\$ (14.2)</b>	<b>\$ (24.8)</b>

***Operating Activities***

Net cash used in operating activities reflects, among other things, the amounts used to run 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, 2013 and 2012 was primarily due to receipt of a \$10 million milestone from Servier in the third quarter of 2013.

***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*

Other than stock option exercises, we had no financing activity in the nine months ended September 30, 2013 or 2012.

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### **Liquidity and Capital Resources**

Since our inception through September 30, 2013, we have raised an aggregate of \$560.7 million to fund our operations. Of this total amount, we have received \$151.3 million from the sale of preferred stock, \$354.9 million from our collaborators, including payments in the form of upfront, milestone and annual maintenance payments and reimbursement for research and development services performed, and \$54.5 million from government grants and contracts. As of September 30, 2013, we had \$33.6 million in cash and cash equivalents.

On October 16, 2013, we completed the IPO of our common stock, which resulted in the sale of 5,750,000 shares, including all additional shares available to cover over-allotments, at a price of \$16.00 per share. We raised \$85.6 million (\$83.8 million net of expenses and deferred financing costs). In connection with the closing of the IPO, all of our outstanding redeemable convertible preferred stock automatically converted to common stock at various ratios as disclosed in our Prospectus.

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, opt-in and annual license maintenance payments and grant revenue. However, our ability to receive these milestone payments is dependent upon our ability to achieve certain levels of 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 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. Based upon our current operating plan, we anticipate that the net proceeds from the IPO together with our existing cash and cash equivalents, and a significant portion of the \$100 million in collaboration payments we anticipate receiving through 2015, will enable us to fund the clinical development of margetuximab, MGA271, MGD006, MGD007 and MGD010 through 2015, assuming all of our collaboration programs advance as currently contemplated.

### **Contractual Obligations and Contingent Liabilities**

There were no material changes to our contractual obligations during the three months ended September 30, 2013. For a complete discussion of our contractual obligations, please refer to our *Management's Discussion and Analysis of Financial Condition and Results of Operations* in the Prospectus.

### **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. As of September 30, 2013, we had cash and cash equivalents of \$33.6 million, of which \$26.0 million was invested in money market funds. Our primary exposure to market risk is related to changes in interest rates and our current investment policy is to invest principally in deposits and securities issued by the U.S. government and its agencies and money market instruments. We do not believe that our cash and cash equivalents have significant risk.

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**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, 2013. 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, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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**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. Many of these statements appear, in particular, under the headings **Risk Factors** and **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**, **could**, **can**, the negatives thereof, variations thereon and similar expressions, or by discussions of strategy.

All forward-looking statements, including, without limitation, our examination of historical operating trends, 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 (including those set forth under **Risk Factors**), 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;

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

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

our failure to maintain effective internal controls.

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Consequently, forward-looking statements should be regarded solely as our current plans, estimates and beliefs. You should not place undue reliance on forward-looking statements. We cannot guarantee future results, events, levels of activity, performance or achievements. 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.

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**PART II. OTHER INFORMATION**

**Item 1A. Risk Factors**

*Our business and results of operations are subject to numerous risks, uncertainties and other factors that you should be aware of, some of which are described below. The risks, uncertainties and other factors described below are not the only ones facing our company. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations.*

*Any of the risks, uncertainties and other factors could have a materially adverse effect on our business, financial condition or results of operations and could cause the trading price of our common stock to decline substantially.*

**Risks Related to Our Business and the Development and Commercialization of Our Product Candidates.**

*All of our product candidates are in pre-clinical or clinical development. Clinical drug development is expensive, time consuming and uncertain and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates.*

The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and non-U.S. regulatory authorities, which regulations differ from country to country. We are not permitted to market our product candidates in the United States or in other countries until we receive approval of a Biologics License Application, or BLA, from the FDA or marketing approval from applicable regulatory authorities outside the United States. Our product candidates are in various stages of development and are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Obtaining approval of a BLA can be a lengthy, expensive and uncertain process. In addition, failure to comply with FDA and non-U.S. regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including:

restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;

restrictions on the products, manufacturers or manufacturing process;

warning letters;

civil and criminal penalties;

injunctions;



suspension or withdrawal of regulatory approvals;

product seizures, detentions or import bans;

voluntary or mandatory product recalls and publicity requirements;

total or partial suspension of production;

imposition of restrictions on operations, including costly new manufacturing requirements; and

refusal to approve pending BLAs or supplements to approved BLAs.

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The FDA and foreign regulatory authorities also have substantial discretion in the drug approval process. The number of pre-clinical studies and clinical trials that will be required for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular drug candidate. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including:

a product candidate may not be deemed safe or effective;

the results may not confirm the positive results from earlier pre-clinical studies or clinical trials;

regulatory agencies may not find the data from pre-clinical studies and clinical trials sufficient;

regulatory agencies might not approve or might require changes to our manufacturing processes or facilities;  
or

regulatory agencies may change their approval policies or adopt new regulations.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. Furthermore, any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product. These limitations may limit the size of the market for the product.

***If clinical trials for our product candidates are prolonged, delayed or stopped, we may be unable to obtain regulatory approval and commercialize our product candidates on a timely basis, which would require us to incur additional costs and delay our receipt of any product revenue.***

We are currently enrolling a Phase 2a clinical trial of margetuximab in patients with metastatic breast cancer and anticipate commencing a Phase 3 potential registration clinical trial of margetuximab in advanced gastroesophageal cancer in the second half of 2014. We have initiated a Phase 1 clinical trial of MGA271 that we expect to complete by the end of 2014. We expect to commence a Phase 1 clinical trial of MGD006 in the first half of 2014 and expect to commence a Phase 1 clinical trial of MGD007 in the second half of 2014. The commencement of these planned clinical trials could be substantially delayed or prevented by several factors, including:

further discussions with the FDA or other regulatory agencies regarding the scope or design of our clinical trials;

the limited number of, and competition for, suitable sites to conduct our clinical trials, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our product candidates;

any delay or failure to obtain regulatory approval or agreement to commence a clinical trial in any of the countries where enrollment is planned;

inability to obtain sufficient funds required for a clinical trial;

clinical holds on, or other regulatory objections to, a new or ongoing clinical trial;

delay or failure to manufacture sufficient supplies of the product candidate for our clinical trials;

delay or failure to reach agreement on acceptable clinical trial agreement terms or clinical trial protocols with prospective sites or clinical research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different sites or CROs; and

delay or failure to obtain institutional review board, or IRB, approval to conduct a clinical trial at a prospective site.

The completion of our clinical trials could also be substantially delayed or prevented by several factors, including:

slower than expected rates of patient recruitment and enrollment;

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failure of patients to complete the clinical trial;

unforeseen safety issues, including severe or unexpected drug-related adverse effects experienced by patients, including possible deaths;

lack of efficacy during clinical trials;

termination of our clinical trials by one or more clinical trial sites;

inability or unwillingness of patients or clinical investigators to follow our clinical trial protocols;

inability to monitor patients adequately during or after treatment by us and/or our CROs; and

the need to repeat or terminate clinical trials as a result of inconclusive or negative results or unforeseen complications in testing.

Changes in regulatory requirements and guidance may also occur and we may need to significantly amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to renegotiate terms with CROs or resubmit clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. Our clinical trials may be suspended or terminated at any time by the FDA, other regulatory authorities, the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or us, due to a number of factors, including:

failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;

lack of adequate funding to continue the clinical trial due to unforeseen costs or other business decisions; and

upon a breach or pursuant to the terms of any agreement with, or for any other reason by, current or future collaborators that have responsibility for the clinical development of any of our product candidates.

Any failure or significant delay in completing clinical trials for our product candidates would adversely affect our ability to obtain regulatory approval and our commercial prospects and ability to generate product revenue will be diminished.

***The results of previous clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or non-U.S. regulatory authorities.***

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any of our current and future collaborators may decide, or regulators may require us, to conduct additional clinical or pre-clinical testing. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Similarly, the outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

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In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and execute a clinical trial to support regulatory approval.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any Phase 2, Phase 3 or other clinical trials we or any of our collaborators may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or other non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 clinical trial that has the potential to result in FDA or other agencies approval. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

***We use new technologies in the development of our product candidates and the FDA and other regulatory authorities have not approved products that utilize these technologies.***

Our products in development are based on new technologies, such as Fc Optimization, bi-specific DARTs and CSLCs. Given the complexity of our technologies, we intend to work closely with FDA and other regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. It is possible that the validation process may take time and resources, require independent third-party analyses or not be accepted by the FDA and other regulatory authorities. For some of our product candidates that are based on these technology platforms, the regulatory approval path and requirements may not be clear, which could add significant delay and expense. Delays or failure to obtain regulatory approval of any of the products that we develop would adversely affect our business.

***We may not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates.***

A key element of our strategy is to use and expand our technology platforms to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of product candidates directed at various cancers and autoimmune disorders, we may not be able to develop product candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize product candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our stock price.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

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***Even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize our products outside of the United States, which would limit our ability to realize their full market potential.***

In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us and may require additional pre-clinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

***We may seek fast-track designation of margetuximab and may seek fast track designation for some of our other product candidates. There is no assurance that the FDA will grant such designation and, even if it does grant fast track designation to margetuximab or one of our other product candidates, that designation may not actually lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval in the United States.***

We may seek fast-track designation of margetuximab and may seek fast track designation and review for some of our other product candidates. If a drug is intended for the treatment of a serious or life-threatening condition or disease, the drug sponsor may apply for FDA fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Moreover, even if we do receive fast track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

***We may seek breakthrough therapy designation by the FDA for any of our product candidates but that is not assured and may not, in any event, lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidates will receive marketing approval in the United States.***

We may apply for breakthrough therapy designation for some of our product candidates. The FDA is authorized to designate a product candidate as a breakthrough therapy if it finds that the product is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA are also eligible for accelerated approval.



Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and, in any event,

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does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

***We may be unable to obtain orphan product designation or exclusivity for some or all of our product candidates. If our competitors are able to obtain orphan product exclusivity for their products that are the same as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, FDA may designate a product candidate as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the European Medicines Agency (EMA) or the FDA from approving another marketing application for the same drug for that time period. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***Our product candidates may have undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.***

Although all of our product candidates have undergone or will undergo safety testing, not all adverse effects of drugs can be predicted or anticipated. Unforeseen side effects from any of our product candidates could arise either during clinical development or, if approved by regulatory authorities, after the approved product has been marketed. All of our product candidates are still in clinical or pre-clinical development. While our clinical trials for our initial product candidates to date have demonstrated a favorable safety profile, the results from future trials may not support this conclusion. The results of future clinical trials may show that our product candidates cause undesirable or unacceptable side effects, which could interrupt, delay or halt clinical trials, and result in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities, or result in marketing approval from the FDA and other regulatory authorities with restrictive label warnings or potential product liability claims.

If any of our product candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products:

regulatory authorities may require us to take our approved product off the market;

regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;

we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;

we may be subject to limitations on how we may promote the product;

sales of the product may decrease significantly;

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we may be subject to litigation or product liability claims; and

our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

***Even if approved, if any of our product candidates do not achieve broad market acceptance among physicians, patients, the medical community, and third-party payors our revenue generated from their sales will be limited.***

The commercial success of our product candidates will depend upon their acceptance among physicians, patients and the medical community. The degree of market acceptance of our product candidates will depend on a number of factors, including:

limitations or warnings contained in the approved labeling for a product candidate;

changes in the standard of care for the targeted indications for any of our product candidates;

limitations in the approved clinical indications for our product candidates;

demonstrated clinical safety and efficacy compared to other products;

lack of significant adverse side effects;

sales, marketing and distribution support;

availability and extent of reimbursement from managed care plans and other third-party payors;

timing of market introduction and perceived effectiveness of competitive products;

the degree of cost-effectiveness of our product candidates;

availability of alternative therapies at similar or lower cost, including generic and over-the-counter products;

the extent to which the product candidate is approved for inclusion on formularies of hospitals and managed care organizations;

whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy for particular diseases;

adverse publicity about our product candidates or favorable publicity about competitive products;

convenience and ease of administration of our products; and

potential product liability claims.

If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, patients and the medical community, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

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***We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our products.***

The process of manufacturing our products is complex, highly regulated and subject to several risks, including:

The process of manufacturing biologics, such as margetuximab, MGA271, and our other product candidates, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, contamination and inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination.

The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

We must comply with the FDA's current Good Manufacturing Practice, or cGMP, regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by the FDA and comparable agencies in other jurisdictions to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill-finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of drug product for our clinical trials or the termination or hold on a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our products. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

***We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, we will not be successful in commercializing our product candidates.***

We currently have no marketing, sales and distribution capabilities and we have no sales or marketing experience within our organization. If any of our product candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates, or to outsource this function to a third party. Either of these options would be expensive and time consuming. These costs may be incurred in advance of any approval of our product candidates. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

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With respect to certain of our existing and future product candidates, we have entered into collaboration or other licensing arrangements with third party collaborators that have direct sales forces and established distribution systems. To the extent that we enter into additional collaboration agreements, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***We face significant competition and if our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our commercial opportunities will be negatively impacted.***

The life sciences industry is highly competitive and subject to rapid and significant technological change. We are currently developing therapeutics that will compete with other drugs and therapies that currently exist or are being developed. Products we may develop in the future are also likely to face competition from other drugs and therapies, some of which we may not currently be aware. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities and other research institutions. Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and/or FDA approval or discovering, developing and commercializing products in our field before we do.

Specifically, there are a large number of companies developing or marketing treatments for cancer and autoimmune disorders, including many major pharmaceutical and biotechnology companies. These treatments consist both of small molecule drug products, as well as biologic therapeutics that work by using next-generation antibody technology platforms to address specific cancer targets. In addition, several companies are developing therapeutics that work by targeting multiple specificities using a single recombinant molecule. Amgen, Inc., or Amgen, is in late-stage clinical development of cancer product candidates which work by targeting antigens both on immune effector cell populations and those expressed on certain cancer cells. In addition, other companies are developing new treatments for cancer and autoimmune diseases that enhance the Fc regions of antibodies to create more potent antibodies, including F. Hoffmann-La Roche Ltd., or Roche, and Xencor, Inc.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third party payors seeking to encourage the use of biosimilar products. Biosimilar products are expected to become available over the coming years. For example, certain HER2 biosimilar products may be approved prior to margetuximab. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive biosimilar products if any have been approved by then.



## Edgar Filing: MACROGENICS INC - Form 10-Q

The Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Affordability Reconciliation Act, or collectively, ACA created a new regulatory scheme authorizing the FDA to approve biosimilars. Under the ACA, a manufacturer may submit an application for licensure of a biologic product that is biosimilar to or interchangeable with a previously approved biological product or reference product. Under this new statutory scheme, an application for a biosimilar product may not be submitted to the

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FDA until four years following approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. Furthermore, recent legislation has proposed that the 12 year exclusivity period for each a reference product may be reduced to seven years.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. In addition, the biopharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

***Reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient reimbursement for our products, it is less likely that our products will be widely used.***

Even if our product candidates are approved for sale by the appropriate regulatory authorities, market acceptance and sales of these products will depend on reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will reimburse and establish payment levels. We cannot be certain that reimbursement will be available for any products that we develop. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, our products. If reimbursement is not available or is available on a limited basis, we may not be able to successfully commercialize any of our approved products.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation established Medicare Part D, which expanded Medicare coverage for outpatient prescription drug purchases by the elderly but provided authority for limiting the number of drugs that will be covered in any therapeutic class. The MMA also introduced a new reimbursement methodology based on average sales prices for physician-administered drugs.

The United States and several foreign jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our future approved products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative proposals.

In March 2010, the ACA became law in the United States. The goal of ACA is to reduce the cost of health care and substantially change the way health care is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, the ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of, and the price we may charge for, any products we develop that receive regulatory

approval. We also cannot predict the impact of ACA on our business or financial condition as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions, which has not yet occurred.

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***If any product liability lawsuits are successfully brought against us or any of our collaborators, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.***

We face an inherent risk of product liability lawsuits related to the testing of our product candidates in seriously ill patients, and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us or our collaborators by participants enrolled in our clinical trials, patients, health care providers or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities. Regardless of their merit or eventual outcome, liability claims may result in:

decreased demand for our future approved products;

injury to our reputation;

withdrawal of clinical trial participants;

termination of clinical trial sites or entire trial programs;

increased regulatory scrutiny;

significant litigation costs;

substantial monetary awards to or costly settlement with patients or other claimants;

product recalls or a change in the indications for which they may be used;

loss of revenue;

diversion of management and scientific resources from our business operations; and

the inability to commercialize our product candidates.

If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity. We could also be adversely affected if any of our products or any similar products distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perceptions, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse

of our products or any similar products distributed by other companies could have a material adverse impact on our financial condition or results of operations.

We currently hold \$15 million in product liability insurance coverage in the aggregate, with a per incident limit of \$15 million, which may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage when we begin the commercialization of our product candidates. Insurance coverage is becoming increasingly expensive. As a result, we may be unable to maintain or obtain sufficient insurance at a reasonable cost to protect us against losses that could have a material adverse effect on our business. A successful product liability claim or series of claims brought against us, particularly if judgments exceed any insurance coverage we may have, could decrease our cash resources and adversely affect our business, financial condition and results of operation.

***Our business may become subject to economic, political, regulatory and other risks associated with international operations.***

Our business is subject to risks associated with conducting business internationally. Some of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

economic weakness, including inflation, or political instability in particular foreign economies and markets;

differing regulatory requirements for drug approvals in foreign countries;

potentially reduced protection for intellectual property rights;

difficulties in compliance with non-U.S. laws and regulations;

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changes in non-U.S. regulations and customs, tariffs and trade barriers;

changes in non-U.S. currency exchange rates and currency controls;

changes in a specific country's or region's political or economic environment;

trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;

negative consequences from changes in tax laws;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

workforce uncertainty in countries where labor unrest is more common than in the United States;

difficulties associated with staffing and managing foreign operations, including differing labor relations;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

**Risks Related to Our Financial Position and Need for Additional Capital**

***We have incurred significant losses since inception and anticipate that we will continue to incur losses for the foreseeable future. We have no products approved for commercial sale, and to date we have not generated any revenue or profit from product sales. We may never achieve or sustain profitability.***

We are a clinical-stage biopharmaceutical company. We have incurred significant losses since our inception. As of September 30, 2013, our accumulated deficit was approximately \$172.0 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates, prepare for and begin to commercialize any approved products, and add infrastructure and personnel to support our product development efforts and operations as a public company. The net losses and negative cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our stockholders' deficit and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve

profitability. For example, our expenses could increase if we are required by the FDA to perform trials in addition to those that we currently expect to perform, or if there are any delays in completing our currently planned clinical trials or in the development of any of our product candidates.

To become and remain profitable, we must succeed in developing and commercializing products with significant market potential. This will require us to be successful in a range of challenging activities for which we are only in the preliminary stages, including developing product candidates, obtaining regulatory approval for them, and manufacturing, marketing and selling those products for which we may obtain regulatory approval. We may never succeed in these activities and may never generate revenue from product sales that is significant enough to achieve profitability. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our failure to become or remain profitable would depress our market value and could impair our ability to raise capital, expand our business, develop other product candidates, or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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***We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not available, may require us to delay, scale back, or cease our product development programs or operations.***

We are advancing our product candidates through clinical development. Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials, is expensive. In order to obtain such regulatory approval, we will be required to conduct clinical trials for each indication for each of our product candidates. We will continue to require additional funding beyond what was raised in the initial public offering, or IPO, of our common stock completed in October 2013 to complete the development and commercialization of our product candidates and to continue to advance the development of our other product candidates, and such funding may not be available on acceptable terms or at all. Although it is difficult to predict our liquidity requirements, based upon our current operating plan, we anticipate that the net proceeds from the IPO, together with our existing cash and cash equivalents and a significant portion of the \$100 million in collaboration payments we anticipate receiving through 2015, will enable us to fund the clinical development of margetuximab, MGA271, MGD006, MGD007 and MGD010 through 2015, assuming all of our collaboration programs advance as currently contemplated. Because successful development of our product candidates is uncertain, we are unable to estimate the actual funds we will require to complete research and development and to commercialize our product candidates.

Our future funding requirements will depend on many factors, including but not limited to:

the number and characteristics of other product candidates that we pursue;

the scope, progress, timing, cost and results of research, pre-clinical development, and clinical trials;

the costs, timing and outcome of seeking and obtaining FDA and non-U.S. regulatory approvals;

the costs associated with manufacturing our product candidates and establishing sales, marketing, and distribution capabilities;

our ability to maintain, expand, and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make in connection with the licensing, filing, defense and enforcement of any patents or other intellectual property rights;

our need and ability to hire additional management, scientific, and medical personnel;

the effect of competing products that may limit market penetration of our product candidates;

our need to implement additional internal systems and infrastructure, including financial and reporting systems; and



the economic and other terms, timing of and success of our existing collaborations, and any collaboration, licensing, or other arrangements into which we may enter in the future, including the timing of receipt of any milestone or royalty payments under these agreements.

Until we can generate a sufficient amount of product revenue to finance our cash requirements, which we may never do, we expect to finance future cash needs primarily through a combination of public or private equity offerings, debt financings, strategic collaborations, and grant funding. If sufficient funds on acceptable terms are not available when needed, or at all, we could be forced to significantly reduce operating expenses and delay, scale back or eliminate one or more of our development programs or our business operations.

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***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish substantial rights.***

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available at all, may involve agreements that include covenants limiting or restricting our ability to take specific actions such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates, or future revenue streams, or grant licenses on terms that are not favorable to us. We cannot assure you that we will be able to obtain additional funding if and when necessary. If we are unable to obtain adequate financing on a timely basis, we could be required to delay, scale back or eliminate one or more of our development programs or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***We have broad discretion in the use of the net proceeds from our IPO and may not use them effectively.***

Our management has broad discretion to use our cash and cash equivalents to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use to fund operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value. ***Our ability to use our net operating loss carryforwards and other tax attributes may be limited.***

Our ability to utilize our federal net operating losses, or NOLs, and federal tax credits is currently limited, and may be limited further, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period, which is typically three years or since the last ownership change. We are already subject to Section 382 limitations due to an acquisition we made in 2008. As of December 31, 2012, we had federal NOL carryforwards of \$100.9 million, state NOL carryforwards of \$64.2 million and research and development tax credit carryforwards of \$21.8 million available. Future changes in stock ownership, may also trigger an ownership change and, consequently, another Section 382 limitation. Any limitation may result in expiration of a portion of the net operating loss or tax credit carryforwards before utilization which would reduce our gross deferred income tax assets and corresponding valuation allowance. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and tax credit carryforwards to reduce United States federal income tax may be subject to limitations, which could potentially result in increased future cash tax liability to us.

### **Risks Related to Our Dependence on Third Parties**

***Our existing therapeutic collaborations are important to our business, and future collaborations may also be important to us. If we are unable to maintain any of these collaborations, or if these collaborations are not successful, our business could be adversely affected.***

We have limited capabilities for drug development and do not yet have any capability for sales, marketing or distribution. Accordingly, we have entered into collaborations with other companies that we believe can provide such

capabilities, including our collaboration and license agreements with Servier, Gilead, Boehringer, Pfizer and Green Cross Corp., or Green Cross. These collaborations also have provided us with important funding for our development programs and technology platforms and we expect to receive additional funding under these collaborations in the future. Our existing therapeutic collaborations, and any future collaborations we enter into, may pose a number of risks, including the following:

collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;

collaborators may not perform their obligations as expected;

collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

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collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;

product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;

a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;

disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;

collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and

collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. For example, each of our collaboration and license agreements with Servier, Gilead, and Boehringer may be terminated for convenience upon the completion of a specified notice period.

If our therapeutic collaborations do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our technology platforms and product candidates could be delayed and we may need additional resources to develop product candidates and our technology platforms. All of the risks relating to product development, regulatory approval and commercialization described in this report also apply to the activities of our program collaborators.

Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators.

For some of our product candidates, we may in the future determine to collaborate with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's

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evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate.

Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our technology platforms and our business may be materially and adversely affected.

We may also be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Aside from our agreement with Green Cross, subject to certain specified exceptions, each of our existing therapeutic collaborations contains a restriction on our engaging in activities that are the subject of the collaboration with third parties for specified periods of time.

***Independent clinical investigators and CROs that we engage to conduct our clinical trials may not devote sufficient time or attention to our clinical trials or be able to repeat their past success.***

We expect to continue to depend on independent clinical investigators and CROs to conduct our clinical trials. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. These investigators and CROs will not be our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any product candidates that we develop. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. Further, the FDA requires that we comply with standards, commonly referred to as current Good Clinical Practice, or cGCP, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Failure of clinical investigators or CROs to meet their obligations to us or comply with cGCP procedures could adversely affect the clinical development of our product candidates and harm our business.

***Failure of our third party contractors to successfully develop and commercialize companion diagnostics for use with our product candidates could harm our ability to commercialize our product candidates.***

We plan to develop companion diagnostics for our product candidates where appropriate. Companion diagnostics are used to identify patients who could potentially benefit from our therapeutic product candidates. We expect that, at least in some cases, the FDA and similar regulatory authorities outside the United States may require the development and regulatory approval of a companion diagnostic as a condition to approving our product candidates. We do not have experience or capabilities in developing or commercializing diagnostics and plan to rely in large part on third parties to perform these functions.

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We plan to outsource the development, production and commercialization of companion diagnostics to third parties. By outsourcing these companion diagnostics to third parties, we become dependent on the efforts of our third party contractors to successfully develop and commercialize these companion diagnostics. Our contractors:

may not perform their obligations as expected;

may encounter production difficulties that could constrain the supply of the companion diagnostic;

may have difficulties gaining acceptance of the use of the companion diagnostic in the clinical community;

may not commit sufficient resources to the marketing and distribution of such product; and

may terminate their relationship with us.

If any companion diagnostic for use with one of our product candidates fails to gain market acceptance, our ability to derive revenues from sales of such product candidate could be harmed. If our third party contractors fail to commercialize such companion diagnostic, we may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with such product candidate or do so on commercially reasonable terms, which could adversely affect and delay the development or commercialization of such product candidate.

***We expect to contract with third parties for the manufacture of our product candidates for clinical testing in the future and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.***

We currently have a manufacturing facility located in Rockville, Maryland. We manufacture drug substance at this facility that we use for research and development purposes and for clinical trials of our product candidates. We currently have capacity to produce Phase 2 material for our antibody product candidates and all clinical and commercial material for our DART therapeutics, but our current facility will be insufficient to support our needs for our Phase 3 clinical trials for our antibody product candidates and for commercial quantities of such candidates. We do not have experience in manufacturing products at commercial scale.

We anticipate engagement of contract manufacturing organizations in 2014 to supplement our clinical supply and internal capacity as we advance pre-clinical product candidates into clinical development. We expect to use third parties for the manufacture of certain of our product candidates for clinical testing, as well as for commercial manufacture of some of our product candidates that receive marketing approval and that are not manufactured by one of our third party collaborators. We plan eventually to enter into long term supply agreements with several manufacturers for commercial supplies. We may be unable to reach agreement with any of these contract manufacturers, or to identify and reach arrangements on satisfactory terms with other contract manufacturers, to manufacture any of our product candidates. Additionally, the facilities used by any contract manufacturer to manufacture any of our product candidates must be the subject of a satisfactory inspection before the FDA and other regulatory authorities approve a BLA or marketing authorization for the product candidate manufactured at that



facility. We will depend on these third-party manufacturing partners for compliance with the FDA's requirements for the manufacture of our finished products. If our manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA and other regulatory authorities' cGMP requirements, our product candidates will not be approved or, if already approved, may be subject to recalls.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

the possibility of a breach of the manufacturing agreements by the third parties because of factors beyond our control;

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the possibility of termination or nonrenewal of the agreements by the third parties before we are able to arrange for a qualified replacement third-party manufacturer; and

the possibility that we may not be able to secure a manufacturer or manufacturing capacity in a timely manner and on satisfactory terms in order to meet our manufacturing needs.

Any of these factors could cause the delay of approval or commercialization of our product candidates, cause us to incur higher costs or prevent us from commercializing our product candidates successfully. Furthermore, if any of our product candidates are approved and contract manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our product candidates and to have any such new source approved by the FDA or any other relevant regulatory authorities.

## **Risks Related to Our Intellectual Property**

***If we are unable to obtain and enforce patent protection for our product candidates and related technology, our business could be materially harmed.***

Issued patents may be challenged, narrowed, invalidated or circumvented. In addition, court decisions may introduce uncertainty in the enforceability or scope of patents owned by biotechnology companies. The legal systems of certain countries do not favor the aggressive enforcement of patents, and the laws of foreign countries may not allow us to protect our inventions with patents to the same extent as the laws of the United States. Because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, or in some cases not at all, and because publications of discoveries in scientific literature lag behind actual discoveries, we cannot be certain that we were the first to make the inventions claimed in our issued patents or pending patent applications, or that we were the first to file for protection of the inventions set forth in our patents or patent applications. As a result, we may not be able to obtain or maintain protection for certain inventions. Therefore, the enforceability and scope of our patents in the United States and in foreign countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against competitors. We may not be able to obtain or maintain patent protection from our pending patent applications, from those we may file in the future, or from those we may license from third parties. Moreover, even if we are able to obtain patent protection, such patent protection may be of insufficient scope to achieve our business objectives.

Our strategy depends on our ability to identify and seek patent protection for our discoveries. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Despite our efforts to protect our proprietary rights, unauthorized parties may be able to obtain and use information that we regard as proprietary. The issuance of a patent does not ensure that it is valid or enforceable, so even if we obtain patents, they may not be valid or enforceable against third parties. In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology. Third parties may also seek to market biosimilar versions of any approved products. Alternatively, third parties may seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend and/or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid and/or unenforceable. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes

sufficient to achieve our business objectives.

The patent position of pharmaceutical or biotechnology companies, including ours, is generally uncertain and involves complex legal and factual considerations. The standards which the United States Patent and Trademark Office, or USPTO, and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. There is also no uniform, worldwide policy regarding the subject matter and scope of claims granted or allowable in pharmaceutical or biotechnology patents. The laws of some

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foreign countries do not protect proprietary information to the same extent as the laws of the United States, and many companies have encountered significant problems and costs in protecting their proprietary information in these foreign countries. Outside the United States, patent protection must be sought in individual jurisdictions, further adding to the cost and uncertainty of obtaining adequate patent protection outside of the United States. Accordingly, we cannot predict whether additional patents protecting our technology will issue in the United States or in foreign jurisdictions, or whether any patents that do issue will have claims of adequate scope to provide competitive advantage. Moreover, we cannot predict whether third parties will be able to successfully obtain claims or the breadth of such claims. The allowance of broader claims may increase the incidence and cost of patent interference proceedings, opposition proceedings, and/or reexamination proceedings, the risk of infringement litigation, and the vulnerability of the claims to challenge. On the other hand, the allowance of narrower claims does not eliminate the potential for adversarial proceedings, and may fail to provide a competitive advantage. Our issued patents may not contain claims sufficiently broad to protect us against third parties with similar technologies or products, or provide us with any competitive advantage.

***We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.***

Even after they have issued, our patents and any patents which we license may be challenged, narrowed, invalidated or circumvented. If our patents are invalidated or otherwise limited or will expire prior to the commercialization of our product candidates, other companies may be better able to develop products that compete with ours, which could adversely affect our competitive business position, business prospects and financial condition.

The following are examples of litigation and other adversarial proceedings or disputes that we could become a party to involving our patents or patents licensed to us:

we or our collaborators may initiate litigation or other proceedings against third parties to enforce our patent rights;

third parties may initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their product or technology does not infringe our patents or patents licensed to us;

third parties may initiate opposition or reexamination proceedings challenging the validity or scope of our patent rights, requiring us or our collaborators and/or licensors to participate in such proceedings to defend the validity and scope of our patents;

there may be a challenge or dispute regarding inventorship or ownership of patents currently identified as being owned by or licensed to us;

the U.S. Patent and Trademark Office may initiate an interference between patents or patent applications owned by or licensed to us and those of our competitors, requiring us or our collaborators and/or licensors to participate in an interference proceeding to determine the priority of invention, which could jeopardize our

patent rights; or

third parties may seek approval to market biosimilar versions of our future approved products prior to expiration of relevant patents owned by or licensed to us, requiring us to defend our patents, including by filing lawsuits alleging patent infringement.

These lawsuits and proceedings would be costly and could affect our results of operations and divert the attention of our managerial and scientific personnel. There is a risk that a court or administrative body would decide that our patents are invalid or not infringed by a third party's activities, or that the scope of certain issued claims must be further limited. An adverse outcome in a litigation or proceeding involving our own patents could limit our ability to assert our patents against these or other competitors, affect our ability to receive royalties or other licensing consideration from our licensees, and may curtail or preclude our ability to exclude third parties from making, using and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

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The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

others may be able to develop a platform that is similar to, or better than, ours in a way that is not covered by the claims of our patents;

others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;

we might not have been the first to make the inventions covered by patents or pending patent applications;

we might not have been the first to file patent applications for these inventions;

any patents that we obtain may not provide us with any competitive advantages or may ultimately be found invalid or unenforceable; or

we may not develop additional proprietary technologies that are patentable.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties.***

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our future approved products or impair our competitive position. For example, certain patents held by third parties cover Fc engineering methods and mutations in Fc regions to enhance the binding of Fc regions to Fc receptors on immune cells. Although we believe that these patents are invalid, if they cover margetuximab or MGA271 and we are unable to invalidate their patents, or if licenses for them are not available on commercially reasonable terms, our business could be harmed, perhaps materially.

Patents that we may ultimately be found to infringe could be issued to third parties. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from developing product candidates using our technology. Our failure to obtain a license to any technology that we require may materially harm our business, financial condition and results of operations. Moreover, our failure to maintain a license to any technology that we require may also materially harm our business, financial condition, and results of operations. Furthermore, we would be exposed to a threat of litigation. Invitrogen, Inc., for example, has asserted that we are required to obtain a license for use of a cell line.

In the pharmaceutical industry, significant litigation and other proceedings regarding patents, patent applications, trademarks and other intellectual property rights have become commonplace. The types of situations in which we may become a party to such litigation or proceedings include:

we or our collaborators may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or processes do not infringe those third parties' patents;

if our competitors file patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;

if third parties initiate litigation claiming that our processes or products infringe their patent or other intellectual property rights, we and our collaborators will need to defend against such proceedings; and

if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our processes or products infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we and our collaborators would need to defend against such proceedings.

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These lawsuits would be costly and could affect our results of operations and divert the attention of our management and scientific personnel. There is a risk that a court would decide that we or our collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our collaborators may not have a viable alternative to the technology protected by the patent and may need to halt work on the affected product candidate or cease commercialization of an approved product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages. An adverse outcome in any litigation or other proceeding could subject us to significant liabilities to third parties and require us to cease using the technology that is at issue or to license the technology from third parties. We may not be able to obtain any required licenses on commercially acceptable terms or at all. Any of these outcomes could have a material adverse effect on our business.

The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

The cost of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the cost of such litigation and proceedings more effectively than we can because of their substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

***If we fail to comply with our obligations under our intellectual property licenses with third parties, we could lose license rights that are important to our business.***

We are currently party to various intellectual property license agreements. These license agreements impose, and we expect that future license agreements may impose, various diligence, milestone payment, royalty, insurance and other obligations on us. For example, we have entered into patent and know-how license agreements which grant us the right to use a certain technology related to biological manufacturing to manufacture margetuximab and MGA271. These licenses typically include an obligation to pay an upfront payment, yearly maintenance payments and royalties on sales. If we fail to comply with our obligations under the licenses, the licensors may have the right to terminate their respective license agreements, in which event we might not be able to market any product that is covered by the agreements. Termination of the license agreements or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms, which could adversely affect our competitive business position and harm our business.

***If we are unable to protect the confidentiality of our proprietary information, the value of our technology and products could be adversely affected.***



In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other proprietary information. To maintain the confidentiality of trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and others upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. Our agreements with

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employees and our personnel policies also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. Thus, despite such agreement, such inventions may become assigned to third parties. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions. To the extent that an individual who is not obligated to assign rights in intellectual property to us is rightfully an inventor of intellectual property, we may need to obtain an assignment or a license to that intellectual property from that individual, or a third party or from that individual's assignee. Such assignment or license may not be available on commercially reasonable terms or at all.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our proprietary information. The disclosure of our trade secrets would impair our competitive position and may materially harm our business, financial condition and results of operations. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to maintain trade secret protection could adversely affect our competitive business position. In addition, others may independently discover or develop our trade secrets and proprietary information, and the existence of our own trade secrets affords no protection against such independent discovery.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously or concurrently employed at research institutions and/or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers, or that patents and applications we have filed to protect inventions of these employees, even those related to one or more of our product candidates, are rightfully owned by their former or concurrent employer. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on our outside counsel to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business. In addition, we are responsible for the payment of patent fees for patent rights that we have licensed from other parties. If any licensor of these patents does not itself elect to make these payments, and we fail to do so, we may be liable to the licensor for any costs and consequences of any resulting loss of patent rights.

***If we do not obtain protection under the Hatch-Waxman Amendments and similar foreign legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.***

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable

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deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

### **Risks Related to Legal Compliance Matters**

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.***

Our research and development involves, and may in the future involve, the use of potentially hazardous materials and chemicals. Our operations may produce hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by local, state and federal laws and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations and fire and building codes, including those governing laboratory procedures, exposure to blood-borne pathogens, use and storage of flammable agents and the handling of biohazardous materials. Although we maintain workers' compensation insurance as prescribed by the States of Maryland and California to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. Additional federal, state and local laws and regulations affecting our operations may be adopted in the future. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

***If we market products in a manner that violates healthcare fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties.***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws commonly referred to as "fraud and abuse" laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include false claims and anti-kickback statutes.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are several statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Most states also have statutes or regulations similar to the federal anti-kickback law and federal false claims laws, which may apply to items such as pharmaceutical products and services reimbursed by private insurers. Administrative, civil and criminal sanctions may be imposed under these federal and state laws.

Over the past few years, a number of pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off-label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. At such time, if ever, as we market any of our future approved products and these products are paid for by governmental programs, it is possible that some of our business activities could also be subject to challenge under one or more of these fraud and abuse laws.

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***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state health care fraud and abuse laws and regulations, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

**Risks Relating to Employee Matters and Managing Growth**

***Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.***

We are highly dependent on the research and development, clinical and business development expertise of Scott Koenig, M.D., Ph.D., our President and Chief Executive Officer, as well as the other members of our senior management, scientific and clinical team. Although we have entered into employment letter agreements with our executive officers, each of them may terminate their employment with us at any time. We currently maintain \$1 million in key person insurance coverage for Dr. Koenig. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. In addition, we will need to expand and effectively manage our managerial, operational, financial, development and other resources in order to successfully pursue our research, development and commercialization efforts for our existing and future product candidates. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

***We will need to grow our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

As of September 30, 2013, we had 160 full-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, sales, marketing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. Also, our management may need to divert a disproportionate amount of their attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations which may result in

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weaknesses in our infrastructure, give rise to operational errors, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of existing and additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates and compete effectively with others in our industry will depend, in part, on our ability to effectively manage any future growth.

**Risks Relating to Our Common Stock**

*Our stock price may be volatile and fluctuate substantially.*

Our stock price is likely to be volatile. The stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology, and other life sciences company stocks. The volatility of pharmaceutical, biotechnology, and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

results and timing of our clinical trials and clinical trials of our competitors' products;

failure or discontinuation of any of our development programs;

issues in manufacturing our product candidates or future approved products;

regulatory developments or enforcement in the United States and foreign countries with respect to our product candidates or our competitors' products;

competition from existing products or new products that may emerge;

developments or disputes concerning patents or other proprietary rights;

introduction of technological innovations or new commercial products by us or our competitors;

announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;

changes in estimates or recommendations by securities analysts, if any cover our common stock;



fluctuations in the valuation of companies perceived by investors to be comparable to us;

public concern over our product candidates or any future approved products;

litigation;

future sales of our common stock;

share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

additions or departures of key personnel;

changes in the structure of health care payment systems in the United States or overseas;

failure of any of our product candidates, if approved, to achieve commercial success;

economic and other external factors or other disasters or crises;

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period-to-period fluctuations in our financial condition and results of operations, including the timing of receipt of any milestone or other payments under commercialization or licensing agreements;

general market conditions and market conditions for biopharmaceutical stocks; and

overall fluctuations in U.S. equity markets.

In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit and divert the time and attention of our management, which could seriously harm our business.

### ***An active trading market for our common stock may not be sustained.***

In October 2013, we closed our IPO. Prior to the IPO, there was no public market for our common stock. Although we have completed our initial public offering and shares of our common stock are listed and trading on The NASDAQ Global Market, an active trading market for our shares may not be sustained. If an active market for our common stock does not continue, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares or sell their shares at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Any inactive trading market for our common stock may also impair our ability to raise capital to continue to fund our operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

### ***Insiders have substantial control over us which could delay or prevent a change in corporate control or result in the entrenchment of management and/or the board of directors.***

Our directors, executive officers and principal stockholders, together with their affiliates and related persons, beneficially own, in the aggregate, approximately 78% of our outstanding common stock. As a result, these stockholders, if acting together, may have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation, or sale of all or substantially all of our assets. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring, or preventing a change in control;

entrenching our management and/or the board of directors;

impeding a merger, consolidation, takeover, or other business combination involving us; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

***We are an emerging growth company and as a result of the reduced disclosure requirements applicable to emerging growth companies, our common stock may be less attractive to investors.***

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or

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revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We could remain an emerging growth company until the earliest to occur of the following:

the last day of the fiscal year in which we have total annual gross revenue of \$1 billion or more;

the last day of our fiscal year following the fifth anniversary of the date of the first sale of common equity securities pursuant to the prospectus filed with the Securities and Exchange Commission on October 11, 2013;

the date on which we have issued more than \$1 billion in non-convertible debt during the previous three years; or

the date on which we are deemed to be a large accelerated filer under SEC rules and regulations.

***We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to corporate governance standards.***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, our administrative staff will be required to perform additional tasks. For example, in anticipation of becoming a public company, we will need to adopt additional internal controls and disclosure controls and procedures, retain a transfer agent and adopt an insider trading policy. As a public company, we will bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the Securities and Exchange Commission and the NASDAQ Global Select Market, have increased legal and financial compliance costs and will make some compliance activities more time consuming. We are currently evaluating these rules, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from our other business activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with our IPO, we increased our directors' and officers' insurance coverage which will increase our insurance cost. In the future, it may be more expensive or more difficult for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

Under the corporate governance standards of the NASDAQ Global Select Market, a majority of our board of directors and each member of our audit committee must be an independent director no later than the first anniversary of the completion of our IPO. We may encounter difficulty in attracting qualified persons to serve on our board of directors and the audit committee, and our board of directors and management may be required to divert significant time and attention and resources away from our business to identify qualified directors. If we fail to attract and retain the required number of independent directors, we may be subject to the delisting of our common stock from the NASDAQ Global Select Market.

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***Provisions of our charter, bylaws, and Delaware law may make an acquisition of us or a change in our management more difficult.***

Certain provisions of our restated certificate of incorporation and restated bylaws that became effective upon the completion of our IPO could discourage, delay, or prevent a merger, acquisition, or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. Stockholders who wish to participate in these transactions may not have the opportunity to do so. Furthermore, since our board of directors is responsible for appointing the members of our management team, these provisions could prevent or frustrate attempts by our stockholders to replace or remove our management by making it more difficult for stockholders to replace members of our board of directors. These provisions:

allow the authorized number of directors to be changed only by resolution of our board of directors;

establish a classified board of directors, providing that not all members of the board of directors be elected at one time;

authorize our board of directors to issue without stockholder approval blank check preferred stock that, if issued, could operate as a poison pill to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that is not approved by our board of directors;

require that stockholder actions must be effected at a duly called stockholder meeting and prohibit stockholder action by written consent;

establish advance notice requirements for stockholder nominations to our board of directors or for stockholder proposals that can be acted on at stockholder meetings;

limit who may call stockholder meetings; and

require the approval of the holders of 75% of the outstanding shares of our capital stock entitled to vote in order to amend certain provisions of our restated certificate of incorporation and restated bylaws.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a prescribed period of time. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders.

***We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.***

We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses. As a result, capital appreciation, if any, of our common stock will be your sole source of gain on your investment for the foreseeable future. Investors seeking cash dividends should not invest in our common stock.

***A significant portion of our total outstanding shares of common stock is restricted from resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. After the IPO in October 2013, we had 25,020,288 outstanding shares of common stock. This includes the shares sold in the IPO, which may be resold in the public market immediately and the remaining shares are currently restricted under securities laws or as a result of lock-up agreements but will be able to be resold as described in the Shares Eligible for Future

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Sale section of the Prospectus. Moreover, holders of an aggregate of 15,504,104 shares of common stock, which includes 15,130,610 shares of common stock issuable upon the conversion of all our outstanding shares of our preferred stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all 1,920,168 shares of common stock that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance and once vested, subject to the lock-up agreements described in the Underwriting section of the Prospectus.

***Future issuances of our common stock or rights to purchase common stock pursuant to our equity incentive plans or outstanding warrants could result in additional dilution of the percentage ownership of our stockholders and could cause our share price to fall.***

As of September 30, 2013, we have options to purchase 2,877,003 shares outstanding under our equity compensation plans. We are also authorized to grant equity awards, including stock options, to our employees, directors and consultants, covering up to 8,170 shares of our common stock, pursuant to our equity compensation plans. We plan to register the number of shares available for issuance or subject to outstanding awards under our equity compensation plans.

***If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.***

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure you that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.



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

***Recent Sales of Unregistered Equity Securities***

In October 2013, upon the closing of our initial public offering, all 294,720,231 shares of our then-outstanding convertible preferred stock were automatically converted into 16,955,790 shares of common stock. The issuance of such shares of common stock was exempt from the registration requirements of the Securities Act of 1933 (Securities Act), pursuant to Section 3(a)(9) and Section 4(s) of the Securities Act.

***Use of Proceeds***

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' full exercise of their option to purchase additional shares, in our initial public offering (the "IPO") at a public offering price of \$16.00 per share, for aggregate gross proceeds of \$92.0 million. All of the shares issued and sold in the IPO 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. Merrill Lynch, Pierce, Fenner & Smith Incorporated and Leerink Swann LLC acted as representatives of the several underwriters. The offering commenced on October 10, 2013 and did not terminate until the sale of all of the shares offered.

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**Item 6. Exhibits**

3.1	Restated Certificate of Incorporation of MacroGenics, Inc. (Incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed on October 17, 2013).
3.2	Amended and Restated By-Laws of MacroGenics, Inc. (Incorporated by reference to Exhibit 3.4 to Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-190994) filed on October 1, 2013).
3.3	Certificate of Correction to the Restated Certificate of Incorporation of MacroGenics, Inc. (Incorporated by reference to Exhibit 3.3 to the Company's Current Report on Form 8-K, filed on October 17, 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

\* In accordance with Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q shall be deemed to be furnished and not filed.

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**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, 2013

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EXHIBIT INDEX

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101.PRE*	XBRL Presentation Linkbase Document

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