OvaScience, Inc.
Form 10-Q
August 13, 2013
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2013

OR

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

For the transition period from to

Commission file number: 000-54647

OVASCIENCE, INC.

(Exact name of registrant as specified in its charter)

Delaware	**45-1472564**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
215 First Street, Suite 240 Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	(Zip Code)

617-500-2802

(Registrant s telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

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

As of August 2, 2013, there were 18,203,156 shares of the registrant s Common Stock, par value $0.001 per share, outstanding.

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OVASCIENCE, INC.

Quarterly Report on Form 10-Q

For the Quarterly Period Ended June 30, 2013

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Part I. Financial Information

Item 1. Financial Statements (Unaudited)

OvaScience, Inc.

(A development stage company)

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

	As of	
	June 30, 2013	**December 31, 2012**
Assets		
Current assets:		
Cash and cash equivalents	$ 28,193	$ 14,776
Short-term investments	26,152	16,615
Prepaid expenses and other current assets	917	574
Total current assets	55,262	31,965
Property and equipment, net	890	756
Other assets	88	93
Total assets	$ 56,240	$ 32,814
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 216	$ 875
Accrued expenses	1,596	1,211
Total current liabilities	1,812	2,086
Other non-current liabilities	15	7
Total liabilities	1,827	2,093
Stockholder s equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, no shares issued and outstanding		
Common stock, $0.001 par value per share; 100,000,000 shares authorized; 18,203,156 and 14,268,068 shares issued at June 30, 2013 and December 31, 2012, respectively; 16,887,037 and 12,622,919 shares outstanding at June 30, 2013 and December 31, 2012, respectively	17	13
Additional paid-in capital	81,709	46,848
Accumulated other comprehensive loss	(26)	(6)
Deficit accumulated during the development stage	(27,287)	(16,134)
Total stockholders equity	54,413	30,721
Total liabilities and stockholders equity	$ 56,240	$ 32,814

See accompanying notes.

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OvaScience, Inc.

(A development stage company)

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(In thousands, except share and per share data)

	Three Months Ended, June 30,		Six Months Ended, June 30,		Period from April 5, 2011 (inception) to June 30,
	2013	2012	2013	2012	2013
Operating expenses:					
Research and development	$ 2,576	$ 1,351	$ 5,256	$ 2,297	$ 12,749
General and administrative	3,445	1,883	5,940	3,903	14,600
Total operating expenses	6,021	3,234	11,196	6,200	27,349
Loss from operations	(6,021)	(3,234)	(11,196)	(6,200)	(27,349)
Interest income	25		43		62
Net loss	$ (5,996)	$ (3,234)	$ (11,153)	$ (6,200)	$ (27,287)
Accretion of convertible preferred stock to redemption value					(101)
Net loss applicable to common stockholders	$ (5,996)	$ (3,234)	$ (11,153)	$ (6,200)	$ (27,388)
Net loss per share applicable to common stockholders basic and diluted	$ (0.36)	$ (2.09)	$ (0.74)	$ (4.22)	$ (4.35)
Weighted average number of common shares used in net loss per share applicable to common stockholders basic and diluted	16,869	1,548	15,132	1,469	6,302
Net loss	$ (5,996)	$ (3,234)	$ (11,153)	$ (6,200)	$ (27,287)
Other comprehensive loss:					
Unrealized losses on available-for-sale securities	(27)		(20)		(26)
Comprehensive loss	$ (6,023)	$ (3,234)	$ (11,173)	$ (6,200)	$ (27,313)
Non-cash stock-based compensation expenses included in operating expenses are as follows:					
Research and development	$ 609	$ 256	$ 1,035	$ 493	$ 2,447
General and administrative	765	43	1,176	113	1,492

See accompanying notes.

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OvaScience, Inc.

(A development stage company)

Condensed Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Six Months Ended June 30,		Period from April 5, 2011 (inception) to June 30,
	2013	**2012**	**2013**
Cash flows from operating activities:			
Net loss	$ (11,153)	$ (6,200)	$ (27,287)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	100	22	193
Accretion of discount (amortization of premium) on debt securities	226		303
Stock-based compensation expense	2,211	559	3,939
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(338)	(165)	(912)
Accounts payable	(659)	328	216
Accrued expenses and other non-current liabilities	393	720	1,612
Net cash used in operating activities	(9,220)	(4,736)	(21,936)
Cash flows from investing activities:			
Purchases of property, plant and equipment	(234)	(456)	(1,083)
Sales and maturities of short-term investments	1,000		1,000
Purchases of short-term investments	(10,783)		(27,481)
Increase in restricted cash		(93)	(93)
Net cash used in investing activities	(10,017)	(549)	(27,657)
Cash flows from financing activities:			
Proceeds from issuance of preferred stock, net of issuance costs		34,992	41,091
Increase in deferred financing costs		(182)	
Net proceeds from the issuance of common stock	32,654	1	36,695
Net cash provided by financing activities	32,654	34,811	77,786
Net increase in cash and cash equivalents	13,417	29,526	28,193
Cash and cash equivalents at beginning of period	14,776	4,541	
Cash and cash equivalents at end of period	$ 28,193	$ 34,067	$ 28,193
Supplemental disclosure of non-cash financing activity			
Accretion of convertible preferred stock to redemption value	$	$	$ (101)
Conversion of convertible preferred stock to common stock	$	$	$ 41,192

See accompanying notes.

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OvaScience, Inc.

(A development stage company)

Notes to Unaudited, Condensed Consolidated Financial Statements

1. Organization and basis of presentation

OvaScience, Inc., incorporated on April 5, 2011 as a Delaware corporation, is a life science company developing proprietary products to improve the treatment of female infertility based on recent scientific discoveries about the existence of egg precursor cells. The Company s operations to date have been limited to organizing and staffing the Company, business planning, raising capital, acquiring and developing its technology, identifying potential product candidates, planning and conducting a marketing study in humans for its most advanced product candidate and undertaking preclinical studies of certain product candidates. The Company has commenced its planned principal operations but has not generated any significant revenues to date. Accordingly, the Company is considered to be in the development stage. As used throughout these unaudited, condensed consolidated financial statements, the terms OvaScience, we, us, and our refer to the business of OvaScience, Inc. and its wholly owned subsidiary.

Liquidity

We have incurred annual net operating losses in each year since our inception. We have not generated any product revenues related to our primary business purpose and have financed our operations primarily through private placements of our preferred stock and common stock. We have not completed development of any product candidate and have devoted substantially all of our financial resources and efforts to raising capital and research and development. We expect to continue to incur significant expenses and increasing operating losses for at least the next several years.

We believe that our cash resources and investments of approximately $54.3 million at June 30, 2013 will be sufficient to allow us to fund our current operating plan through 2014. We will be required to obtain additional funding in order to continue to fund our operations after 2014. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

2. Significant accounting policies

Unaudited interim financial data

The accompanying unaudited condensed consolidated June 30, 2013 balance sheet, the statements of operations and comprehensive loss for the three and six months ended June 30, 2013 and 2012, and the statements of cash flows for the six months ended June 30, 2013 and 2012, and the

related interim information contained within the notes to the financial statements, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission for interim financial information. Accordingly, they do not include all of the information and the notes required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, the unaudited interim financial statements reflect all adjustments, consisting of normal and recurring adjustments, necessary for the fair statement of our financial position at June 30, 2013 and results of our operations for the three and six months ended June 30, 2013 and 2012 and our cash flows for the six months ended June 30, 2013 and 2012. The results for the three and six months ended June 30, 2013 are not necessarily indicative of future results.

Principles of consolidation

These condensed consolidated financial statements include the accounts of OvaScience and the accounts of our wholly-owned subsidiary, OvaScience Securities Corporation. All intercompany transactions have been eliminated in consolidation.

Use of estimates

These condensed consolidated financial statements are presented in conformity with U.S. generally accepted accounting principles which require management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from such estimates.

Segment and geographic information

We make operating decisions based upon the performance of the enterprise as a whole and utilize our consolidated financial statements for decision making. We operate in one business segment, which focuses on developing product candidates dedicated to the treatment of female infertility. We currently operate in only one geographic segment.

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Comprehensive loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss for the three and six months ended June 30, 2013 and 2012, and the period from April 5, 2011 (inception) to June 30, 2013, comprised net loss and unrealized gains and losses on short-term investments. During the three and six months ended June 30, 2013, there were no reclassifications out of other comprehensive loss.

Cash equivalents and short-term investments

Cash equivalents and short-term investments primarily consist of money market funds and corporate obligations. Corporate obligations include obligations issued by corporations in countries other than the United States, including some issues that have not been guaranteed by governments and government agencies. We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents. Cash equivalents, which consist of money market funds are stated at fair value. They are also readily convertible to known amounts of cash and have such short-term maturities that each presents insignificant risk of change in value due to changes in interest rates. The classification of cash equivalents is consistent with prior periods.

The appropriate classification of marketable securities is determined at the time of purchase and reevaluated at each balance sheet date. We have classified all of our short-term investments at June 30, 2013 and December 31, 2012 as available-for-sale. We carry available-for-sale securities at fair value, with the unrealized gains and losses reported in accumulated other comprehensive income (loss), which is a separate component of stockholders equity.

The cost of available-for-sale debt securities are adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in interest and investment income. The cost of securities sold is based on the specific identification method. Interest and dividends on securities classified as available-for-sale are included in investment income.

We conduct periodic reviews to identify and evaluate each investment that is in an unrealized loss position in order to determine whether an other-than-temporary impairment exists. An unrealized loss exists when the current fair value of an individual security is less than its amortized cost basis. Unrealized losses on available-for-sale debt securities that are determined to be temporary, and not related to credit loss, are recorded, net of tax, in accumulated other comprehensive income (loss).

For available-for-sale debt securities in an unrealized loss position, we perform an analysis to assess whether we intend to sell or whether we would more likely than not be required to sell the security before the expected recovery of the amortized cost basis. Where we intend to sell a security, or may be required to do so, the security s decline in fair value is deemed to be other-than-temporary and the full amount of the unrealized loss is recorded within the statement of operations as an impairment loss.

Regardless of our intent to sell a security, we perform an additional analysis on all securities in an unrealized loss position to evaluate losses associated with the creditworthiness of the security. Credit losses are identified where we do not expect to receive cash flows sufficient to

recover the amortized cost basis of a security and are recorded within earnings as an impairment loss.

Income Taxes

We use the liability method to account for income taxes. Deferred tax assets and liabilities are determined based on differences between financial reporting and income tax basis of assets and liabilities, as well as net operating loss and tax credit carryforwards, and are measured using the enacted tax rates and laws that will be in effect when the differences reverse. Deferred tax assets are reduced by a valuation allowance to reflect the uncertainty associated with their ultimate realization. The effect of a change in tax rate on deferred taxes is recognized in income or loss in the period that includes the enactment date.

We use our judgment for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Any material interest and penalties related to unrecognized tax benefits are recognized in income tax expense.

Due to the uncertainty surrounding the realization of the net deferred tax assets in future periods, we have recorded a full valuation allowance against our otherwise recognizable net deferred tax assets as of June 30, 2013 and December 31, 2012.

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Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. We determine fair value based on the assumptions market participants use when pricing the asset or liability. We also use the fair value hierarchy that prioritizes the information used to develop these assumptions.

Our available-for-sale securities are valued utilizing third party pricing services. The pricing services use many observable market inputs to determine value, including benchmark yields, reportable trades, broker/dealer quotes, issuer spreads, two-sided markets, benchmark securities, bids, offers, reference data, new issue data, monthly payment information and collateral performance. We validate the prices provided by our third party pricing services by understanding the models used, obtaining market values from other pricing sources, and confirming that those securities trade in active markets.

Concentrations of credit risk and off-balance sheet risk

Cash, cash equivalents and marketable securities are the only financial instruments that are potentially subject to concentrations of credit risk. We maintain our cash, cash equivalents and short-term investments with a high quality, accredited financial institution and, accordingly, such funds are subject to minimal credit risk. We have also established guidelines relating to diversification and maturities that allow us to manage risk. We have no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

Research and development costs

Research and development costs are expensed to operations as incurred. Research and development expenses consist of costs associated with research activities, including license payments paid to third parties for rights to intellectual property, the costs of development of therapeutic product candidates and advances in the field of infertility. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made. Research and development expenses consist of:

- employee-related expenses, including salaries, benefits, travel and stock-based compensation expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations manufacturing organizations and consultants;
- license fees; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and laboratory and other supplies.

Stock-based compensation

The fair value of employee stock options is expensed on a straight-line basis over the requisite service period, which is the vesting period. Compensation expense is measured using the fair value of the award at the grant date, net of estimated forfeitures, and is adjusted to reflect actual forfeitures. The fair value of each stock option is estimated using the Black-Scholes option pricing model.

Stock-based awards issued to non-employees, including directors for non-board related services, are accounted for based on the fair value of such services received or of the equity instruments issued, whichever is more reliably measured. These stock-based option awards are revalued at the end of each fiscal quarter using the fair value method.

Property and equipment

Property and equipment is stated at cost. Expenditures for repairs and maintenance are recorded to expense as incurred, whereas major betterments are capitalized as additions to property and equipment. Depreciation expense is recorded over the following estimated useful lives of the assets:

Laboratory equipment	5 years
Furniture	5 years
Computer equipment	3 years
Leasehold improvements	Shorter of asset life or lease term

Upon retirement or sale, the cost of the disposed asset and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is recognized.

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We review our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying value of assets may not be fully recoverable and that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted cash flow to the recorded value of the asset. If impairment is indicated, the asset will be written down to its estimated fair value. To date, no such impairment losses have been recorded.

Net loss per share

Basic and diluted net loss per common share is calculated by dividing net loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Potentially dilutive shares include preferred stock, outstanding stock options and unvested restricted stock are only included in the calculation of diluted net loss per share when their effect is dilutive.

The amounts in the table below were excluded from the calculation of diluted net loss per share, prior to the use of the treasury stock method, due to their anti-dilutive effect (in thousands):

	At June 30,	
	2013	**2012**
Series A preferred stock		3,065
Series B preferred stock		6,771
Outstanding stock options and restricted stock units	2,170	687
Founders stock	1,316	1,974

3. Fair value

We use a valuation hierarchy for disclosure of the inputs used to measure fair value. This hierarchy prioritizes the inputs into three broad levels. Level 1 inputs, which are considered the highest level inputs, are quoted prices (unadjusted) in active markets for identical assets or liabilities. Level 2 inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument. Level 3 inputs are unobservable inputs based on our assumptions used to measure assets and liabilities at fair value. For fixed income securities, we reference pricing data supplied by our custodial agent and nationally known pricing vendors, using a variety of daily data sources, largely readily-available market data and broker quotes. The prices provided by third party pricing services are validated by reviewing their pricing methods and obtaining market values from other pricing sources. After completing these validation procedures, we did not adjust or override any fair value measurements provided by the pricing services as of June 30, 2013 or December 31, 2012.

The following table provides the assets carried at fair value measured on a recurring basis as of June 30, 2013:

	Level 1	**Level 2**
	(in thousands)	
Assets:		

Cash and money market funds	$ 28,193	$
Corporate obligations (including commercial paper)		26,152
Total	$ 28,193	$ 26,152

There have been no changes to the valuation methods during the three and six months ended June 30, 2013. There were no transfers of assets or liabilities between Level 1 and Level 2 during the three and six months ended June 30, 2013. We had no short-term investments that were classified as Level 3 at any point during the three and six months ended June 30, 2013 or during the year ended December 31, 2012.

The carrying amounts reflected in the consolidated balance sheets for prepaid expenses and other current assets, other assets, accounts payable and accrued expenses approximate fair value due to their short term maturities.

4. Cash, cash equivalents and short-term investments

The following tables summarize our cash, cash equivalents and marketable securities at June 30, 2013 and December 31, 2012 (in thousands):

As of June 30, 2013	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 28,193	$	$	$ 28,193
Corporate debt securities				
Due in one year or less	20,251	1	(16)	20,236
Due in two years or less	5,927		(11)	5,916
Total	$ 54,371	$ 1	$ (27)	$ 54,345
Reported as:				
Cash and cash equivalents	$ 28,193	$	$	$ 28,193
Short-term investments	26,178	1	(27)	26,152
Total	$ 54,371	$ 1	$ (27)	$ 54,345

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As of December 31, 2012	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Cash and money market funds	$ 14,776	$	$	$ 14,776
Corporate debt securities				
Due in one year or less	5,754	2	(1)	5,755
Due in two years or less	10,867	3	(10)	10,860
Total	$ 31,397	$ 5	$ (11)	$ 31,391
Reported as:				
Cash and cash equivalents	$ 14,776	$	$	$ 14,776
Marketable securities	16,621	5	(11)	16,615
Total	$ 31,397	$ 5	$ (11)	$ 31,391

We held 21 debt securities at June 30, 2013 that had been in an unrealized loss position for less than 12 months. We held no investments that have been in a continuous unrealized loss position for 12 months or longer. The fair value on these securities was $20.2 million. We evaluated our securities for other-than-temporary impairments based on quantitative and qualitative factors. We considered the decline in market value for these 21 securities to be primarily attributable to current economic and market conditions. It is not more likely than not that we will be required to sell these securities, and we do not intend to sell these securities before the recovery of their amortized cost bases, which recovery is expected within the next 12 months. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of June 30, 2013.

As of June 30, 2013, we held $13.3 million in financial institution debt securities and other corporate debt securities located in Canada, the United Kingdom, the Netherlands, Australia, and Norway. Based on our analysis, we do not consider these investments to be other-than-temporarily impaired as of June 30, 2013.

We had no material realized gains or losses on our short-term investments for the three months and six months ended June 30, 2013 and 2012. There were no other-than-temporary impairments recognized for the three months and six months ended June 30, 2013 and 2012.

5. Common stock

In March 2013, we issued and sold in a private placement an aggregate of 3,888,880 shares of our common stock to investors at $9.00 per share. The private placement resulted in $32,652,000 of net proceeds. Related legal and accounting fees for the private placement were recorded as an offset to additional paid-in-capital. In connection with the private placement, we agreed to file a registration statement covering the resale of all such shares.

6. Stock-based compensation

The following table summarizes share-based compensation expense included within our condensed consolidated statements of operations:

	Three Months Ended, June 30,		Six Months Ended, June 30,		Period from April 5, 2011 (inception) to June 30,
	2013	2012	2013	2012	2013
Research and development	$ 609	$ 256	$ 1,035	$ 493	$ 2,447
General and administrative	765	43	1,176	113	1,492

On December 5, 2012, we issued a total of 192,308 restricted stock units (RSUs) to its Chief Executive Officer. This grant included 128,205 RSUs with time-based vesting as follows: 16,025 shares on March 31, 2013 and 16,025 shares each quarter thereafter until December 31, 2014. The grant also included 64,103 RSUs that will vest only upon the achievement of performance conditions that relate to 2013 and 2014 as determined by our board of directors. On March 20, 2013, the board of directors established the 2013 performance criteria for the first tranche of the award and communicated the performance criteria to the grant recipient. The weighted average exercise price is $0.001 per share for these awards, and the grant date stock price was $10.00 per share. We have reviewed the performance conditions and deemed the conditions probable of achievement. The fair value of the time-based RSUs is based on the closing price of our common stock on the award date, or $7.80 per share. The stock-based compensation expense for this grant is being

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recognized on a straight-line basis over the vesting period for the portion of the award that is probable of vesting. The Company recognized total stock-based compensation for the time-based awards and performance based awards of $220,311 and $351,439 for the three and six months ended June 30, 2013.

Included within the general and administrative expense for the three and six months ended June 30, 2013 is expense related to the RSUs with performance-based vesting provisions that will vest on December 31, 2013, based on our determination that certain defined performance metrics are probable of achievement. The performance metrics for the RSUs that will vest on December 31, 2014 have not been established and therefore we have not recorded any expense related to those RSUs.

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

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012
Volatility	83 - 86%	84 - 87%	83 91%	84 - 87%
Risk-free interest rate	1.2 1.4%	0.8 - 1.2%	0.9 1.4%	0.8 - 1.2%
Dividend yield				
Expected term	5.3 - 6.1	5.1 - 6.1	5.3 - 6.1	5.1 - 6.1

The computation of expected volatility is based on the historical volatility of a representative group of companies with similar characteristics to the Company, including stage of product development and life science industry focus. The representative group of companies consisted of NeoGenomics, Inc., StemCells, Inc., BioSante Pharmaceuticals, Inc., Sangamo Biosciences, Inc., and Concept Therapeutics, Inc. As a result of being a development stage company in a very early stage of product development with no revenues, the representative group of companies has certain similar, but not all similar, characteristics to the Company. We believe the group selected has sufficient similar economic and industry characteristics and includes companies that are most representative of OvaScience.

As of June 30, 2013, we had approximately $14.2 million of total unrecognized compensation cost, net of estimated forfeitures, related to unvested stock options and restricted stock units, which are expected to be recognized over a weighted-average period of 3.0 years.

During the three and six months ended June 30, 2013, we granted options to purchase 403,880 and 841,422 shares of our common stock at a weighted average grant date fair value of $9.90 and $9.65, respectively, and with a weighted average exercise price of $14.00 and $13.37, respectively. During the three and six months ended June 30, 2012, we granted options to both employees and non-employees to purchase 94,120 and 167,275 shares of our common stock, respectively and with a weighted average exercise price of $4.53 and $4.30, respectively. The employee options were granted at a weighted average fair value of $3.35 and $3.15, for the three and six months ended June 30, 2012, respectively. The non-employee options are subject to mark-to-market accounting at the end of each period.

7. Subsequent events

In preparing the financial statements included, we evaluated all subsequent events that occurred after June 30, 2013 through the date of the filing of this Form 10-Q. We did not have any material recognizable or unrecognizable subsequent events during this period.

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

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. The statements contained in this Quarterly Report on Form 10-Q that are not purely historical are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Without limiting the foregoing, the words may, will, should, could, expects, plans, intends, anticipates, believes, estimates, predicts, potential, continue, target, goal and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. All forward-looking statements included in this Quarterly Report on Form 10-Q are based on information available to us up to, and including, the date of this document, and we expressly disclaim any obligation to update any such forward-looking statements to reflect events or circumstances that arise after the date hereof. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain important factors, including those set forth in this Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations, as well as under Part II, Item 1A Risk Factors and elsewhere in this Quarterly Report on Form 10-Q. You should carefully review those factors and also carefully review the risks outlined in other documents that we file from time to time with the Securities and Exchange Commission, or SEC.

Overview

We are a life science company developing proprietary products to improve the treatment of female infertility based on recent scientific discoveries about the existence of egg precursor cells. In 2004, one of our scientific founders, Jonathan Tilly, Ph.D., discovered the existence of egg precursor cells within the ovaries of adult mice. Subsequent research by Dr. Tilly demonstrated that these egg precursor cells also exist in human ovaries and have the potential to mature into eggs and, therefore, to replenish a woman s egg supply. These discoveries put into question the long held belief that a woman is born with a finite number of eggs. This research also demonstrated that these egg precursor cells might provide a source of fresh cellular components, such as mitochondria, that could potentially be used to enhance the quality of existing eggs.

We hold an exclusive license from MGH to an issued patent and various patent applications directed to methods of identifying and purifying egg precursor cells, compositions comprising egg precursor cells and methods of using egg precursor cells to treat infertility and related disorders. In August 2013, we acquired a patent and pending application related to the culture of ovarian cells. We are working to develop product candidates based on these egg precursor cell discoveries, with the goal of improving the success of *in vitro* fertilization, or IVF. In an IVF procedure, a woman s own eggs, or the eggs of a donor, are fertilized outside of the woman s body and the resulting embryos are transferred back into the woman s uterus.

Although this research has demonstrated the existence of egg precursor cells in human ovaries, and suggests that it may be possible to develop human egg precursor cells into mature, fertilizable eggs, research with respect to human egg precursor cells is a new and emerging field. As a result, there is ongoing debate regarding the role of egg precursor cells in human reproduction and whether egg precursor cells, when isolated from ovarian tissue, can be matured in the laboratory into fertilizable human eggs.

Our Product Candidates

AUGMENT

Our first product candidate is AUGMENT, which stands for autologous germline mitochondria energy transfer. We are designing AUGMENT to increase the success of IVF by isolating fresh mitochondria from a woman s own egg precursor cells and then adding the mitochondria into the woman s egg during IVF. Mitochondria are the structures within cells responsible for energy production. As a result of the passage of time and other factors, the eggs of women of advanced reproductive age often contain mitochondria that produce inadequate amounts of energy. We believe that by supplementing preexisting egg mitochondria with fresh mitochondria from egg precursor cells we will improve the likelihood that, after fertilization, the egg will develop into a viable embryo and thereby reduce the number of IVF cycles as well as the number of embryos transferred per cycle required to achieve a live birth. In December 2012, we initiated a study in the United States in which 40 women aged 38 to 42 who have failed two to five IVF cycles will receive AUGMENT to assess both safety and effectiveness. As part of the study, we will collect data on an additional group of women who have not received AUGMENT for a comparison group. We refer to this study as our AUGMENT Study. We have initiated commercial preparations for AUGMENT and, assuming the results of the AUGMENT Study are positive, plan to begin generating revenues from AUGMENT in the second half of 2014. As data from the AUGMENT Study in humans in the United States becomes available, we will seek to commercialize AUGMENT in certain other markets in the second half of 2014. We currently expect we would commercialize AUGMENT on our own in select countries and consider potential partnerships for other countries. In support of our commercial strategy, we are adding clinical sites and plan to enroll additional patients beyond the planned 40 patients, which we refer to as the Expansion Study. We plan to enroll patients in AUGMENT outside of the United States beginning in the first half of 2014. We do not believe we will be required to seek premarket approval or clearance of AUGMENT

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from regulatory authorities in the United States or certain other countries. Thus our current financial and business plans assume that we will not need to seek or obtain pre-marketing approval for AUGMENT in the United States.

OvaTure

Our second product candidate is OvaTure. We have, and will continue to optimize, the design of our OvaTure program as a potential next generation of IVF. OvaTure involves the creation of mature fertilizable eggs from a woman s own egg precursor cells. If successful, this would allow women with compromised eggs due to age or other factors to undergo IVF using their own higher quality eggs. In addition, we believe OvaTure would reduce or eliminate the need for hormonal hyperstimulation for egg retrieval in the IVF process. Hormonal hyperstimulation is used in IVF to cause the maturation of multiple eggs. It is associated with significant side effects and is not appropriate for use by all women, for example, women with hormone-dependent cancers. We initiated development of OvaTure in 2012, and we conducted proof of concept studies in animals. We seek to demonstrate human proof of concept studies in which we mature egg precursor cells ex vivo, or outside the body, into fertilizable eggs using our defined culture conditions, and to initiate in 2014 further Investigational New Drug Application / European Clinical Trial Application enabling studies. We expect we will need to obtain regulatory approval of OvaTure in both the United States and the European Union prior to commercialization.

Other Product Opportunities

We also plan to develop and may acquire additional product offerings related to the treatment of female infertility. We are currently considering two opportunities:

- development of IVF culture media, which is the solution used to provide nutrients for eggs and embryos in the IVF process, that can increase the activity of mitochondria; and

- cryopreservation, or banking, of egg precursor cells for future fertility treatments.

Critical Accounting Policies and Significant Judgments and Estimates

The discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates, including those related to accrued expenses and assumptions in the valuation of stock-based compensation. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ from those estimates.

Please read Part II, Item 7 Management s Discussion and Analysis of Financial Condition and Results of Operations of our Annual Report on Form 10-K for the year ended December 31, 2012 for a discussion of our critical accounting policies and estimates.

There were no significant changes to our critical accounting policies and estimates in the six months ended June 30, 2013.

We have irrevocably elected not to follow the extended transition period available to emerging growth companies provided for in Securities Act Section 7(a)(2)(B) for complying with new or revised accounting standards.

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Results of Operations

The following tables summarize our results of operations for each of the three and six months ended June 30, 2013 and 2012, together with the change in these items in dollars and as a percentage:

	Three Months Ended, June 30,			Six Months Ended, June 30,		
	2013	2012	% Change	2013	2012	% Change
Research and development	$ 2,576	$ 1,351	91%	$ 5,256	$ 2,297	129%
General and administrative	3,445	1,883	83%	5,940	3,903	52%
Interest income	25		N/A	43		N/A

Revenue

To date, we have not generated any revenue. Our ability to generate revenue, which we do not expect will occur prior to the second half of 2014, if ever, will depend heavily on the successful development and eventual commercialization of AUGMENT and our other product candidates.

Research and Development Expenses

The $1.2 million or 91% increase in research and development expense for the three months ended June 30, 2013 as compared to the three months ended June 30, 2012 was primarily attributable to:

- higher contract research organization expenses and consulting fees of $0.4 million, comprised of expenses for outsourced biology, chemistry, clinical and development services;
- increased stock-based compensation expense of $0.4 million both for employees and non-employees; and
- higher payroll expense of $0.2 million, including salaries, bonus, payroll taxes and benefits for our employees in research and development, due to increased research and development headcount;

The $3.0 million or 129% increase in research and development expense for the six months ended June 30, 2013 as compared to the six months ended June 30, 2012 was primarily attributable to:

- higher contract research organization expenses and consulting fees of $1.5 million, comprised of expenses for outsourced biology, chemistry, clinical and development services;

- higher stock-based compensation expense of $0.5 million both for employees and non-employees; and

- increased payroll expense of $0.5 million, including salaries, bonus, payroll taxes and benefits for our employees in research and development, due to increased research and development headcount.

We do not maintain or evaluate, and therefore do not allocate, internal research and development costs on a project-by-project basis. We do not have actual external or total expenses by project for the inception to date or the three or six months ended June 30, 2013 and June 30, 2012. Substantially all research and development expenses related to the development of AUGMENT.

We expect our expenses to increase significantly in connection with our ongoing and future activities, particularly as we continue with the AUGMENT and OvaTure programs. See Part II, Item 1A Risk Factors: (*we will need substantial additional funding).*

General and Administrative Expenses

The $1.6 million or 83% increase in general and administrative expense for the three months ended June 30, 2013 as compared to the three months ended June 30, 2012 was primarily due to:

- increased stock-based compensation expense of $0.7 million, due to increased headcount and restricted stock units granted in December of 2012.

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- higher consulting and commercial preparation expenses of $0.4 million; and

- increased payroll expense of $0.4 million, including salaries, bonus, payroll taxes and benefits for our employees in general and administrative functions primarily due to increased headcount.

The $2.0 million or 52% increase in general and administrative expense for the six months ended June 30, 2013 as compared to the six months ended June 30, 2012 was primarily due to:

- increased stock-based compensation expense of $1.1 million, due to increased headcount, restricted stock units granted in December of 2012 and the higher fair value of our common stock; and

- higher consulting and commercial preparation expenses of $0.8 million.

Interest Income

Interest income increased in the three and six months ended June 30, 2013 as compared to the three and six months ended June 30, 2012 primarily due to a higher average balance of our cash equivalents and short-term investments.

Liquidity and Capital Resources

Sources of Liquidity

We have not generated any commercial sales to date, and we do not expect to generate any such sales for the next several years, if at all. We have relied on the proceeds from sales of equity securities to fund our operations. Our short-term investments primarily trade in liquid markets, and the average days to maturity of our portfolio as of June 30, 2013 is less than six months.

Our significant capital resources are as follows:

	June 30, 2013	December 31, 2012
	(in thousands)	
Cash, cash equivalents and short-term investments	$ 54,345	$ 31,391
Working capital	53,450	29,879

	Six Months Ended June 30,		Period from April 5, 2011 (inception) to June 30, 2013
	2013	2012	
	(in thousands)		
Cash provided by (used in):			
Operating activities	$ (9,220)	$ (4,736)	$ (21,936)
Investing activities	(10,017)	(549)	(27,657)
Capital expenditures (included in investing activities above)	(234)	(456)	(1,083)
Financing activities	32,654	34,811	77,786

Cash Flows

The principal use of cash in operating activities in all of the periods presented was the funding of our net loss. Cash flows from operations can vary significantly due to various factors, including changes in accounts payable and accrued expenses. Cash flow from operations includes a decrease in accounts payable primarily resulting from payments made to a contract research organization.

Net cash from investing activities for the six months ended June 30, 2013 included $10.8 million in purchases of short-term investments and proceeds of $1.0 million from maturities of short-term investments. Capital expenditures in the six months ended June 30, 2013 primarily consisted of laboratory equipment.

Net cash from financing activities for the six months ended June 30, 2013 was primarily the result of the private placement of an aggregate of 3,888,880 shares of common stock at a price per share of $9.00 resulting in net proceeds of $32.7 million.

Funding Requirements

Assuming we have no revenue from product sales, we expect our existing cash, cash equivalents and marketable securities of $54.3 million at June 30, 2013 will enable us to fund our current operating plan through 2014. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of

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the numerous risks and uncertainties associated with the development and commercialization of our product candidates, and the extent to which we may enter into collaborations with third parties for development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our current product candidates. Our future capital requirements will depend on many factors, including:

- the timing and results of our AUGMENT Study and Expansion Study;
- our ability to successfully commercialize AUGMENT;
- the costs and timing of commercialization activities for AUGMENT, including manufacturing, sales, marketing and distribution;
- revenue, if any, received from commercial activities of AUGMENT or any other product candidates;
- the scope, progress, results and costs of research, preclinical development, and clinical trials for our product candidates including OvaTure;
- the regulatory process, including the premarketing and marketing approval requirements, to which some of our product candidates could or will be subject;
- the costs, timing and outcome of regulatory review of our product candidates that are subject to such review;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish collaborations and partnerships on favorable terms, if at all; and
- the extent to which we develop, acquire or in-license other products and technologies.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing, if available, 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, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Recently Adopted Accounting Standards

There are no recently issued accounting standards that have a material impact on us.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our interest income is sensitive to changes in the general level of U.S. interest rates, particularly since a significant portion of our investments are in money market funds and corporate obligations. We do not enter into investments for trading or speculative purposes. Our cash is deposited in and invested through highly rated financial institutions in North America. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase.

A hypothetical 100 basis point increase in interest rates would result in an approximate $0.2 million decrease in the fair value of our investments as of June 30, 2013, as compared to an approximate $0.2 million decrease as of December 31, 2012. We have the ability to hold our fixed income investments until maturity and, therefore, we do not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2013. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2013, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Controls. No change in our internal control over financial reporting occurred during the fiscal quarter ended June 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II. Other Information

Item 1. Legal Proceedings

We are not party to any material legal proceedings.

Item 1A. Risk Factors

Our business is subject to numerous risks. We caution you that the following important factors, among others, could cause our actual results to differ materially from those expressed in forward looking statements made by us or on our behalf in filings with the SEC, press releases, communications with investors and oral statements. Any or all of our forward looking statements in this Quarterly Report on Form 10-Q and in any other public statements we make may turn out to be wrong. They can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors mentioned in the discussion below will be important in determining future results. Consequently, no forward looking statement can be guaranteed. Actual future results may differ materially from those anticipated in forward looking statements. We undertake no obligation to update any forward looking statements, whether as a result of new information, future events or otherwise. You are advised, however, to consult any further disclosure we make in our reports filed with the SEC.

The following discussion includes risk factors that have been revised since our Annual Report on Form 10-K for the year ended December 31, 2012 (We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability. ; We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts. ; The science underlying our principal product candidates is based on recent discoveries, and OvaTure has not been tested in humans. ; We have entered into an agreement with a third party for the manufacture of AUGMENT and expect to rely on third parties for the manufacture of our other product candidates for preclinical testing, clinical trials, and commercialization. ; If we fail to comply with our obligations under our intellectual property licenses, we could lose license rights that are important to our business. ; Lack of coordination internally among our employees and externally with physicians, IVF clinics and third party suppliers and carriers could result in processing and manufacturing difficulties, regulatory and enforcement actions, disruptions or delays and cause us to have insufficient product to meet our expected AUGMENT Study requirements or potential commercial requirements; and the risk factors listed under the heading Risks Associated with Our Capital Stock) to reflect recent developments.

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Risks Related to Our Financial Position and Need for Additional Capital

Our short operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We commenced active operations in April 2011. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, identifying potential product candidates, planning for and enrolling patients for our AUGMENT Study, and determining the preclinical and clinical path for our other product candidates including OvaTure. We have not yet commenced commercial sale of any product and have not yet demonstrated our ability to initiate or successfully complete any clinical studies, obtain marketing approvals or conduct sales, marketing and other activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. We will need to transition from a company focused on in-licensing and research to a company capable of developing multiple product candidates and supporting commercial activities. We may not be successful in such a transition.

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Since our inception, we have incurred significant operating losses. Our net loss was $6.0 million and $11.2 million for the three and six months ended June 30, 2013, respectively, and $27.3 million for the period from April 5, 2011 (inception) to June 30, 2013. To date, we have not generated any revenues and have financed our operations through private placements of our Series A preferred stock, Series B preferred stock and common stock. We have devoted substantially all of our efforts to acquiring our technology and developing AUGMENT. We initiated our AUGMENT Study in December 2012 and continue to enroll patients. In addition, we are conducting preclinical development in OvaTure. Although we have initiated commercial preparations for AUGMENT and, assuming the results of our AUGMENT Study are positive, plan to begin generating revenues from AUGMENT in the second half of 2014, we may not be able to do so on our current timeline, or at all. In addition, we expect that it will be many years, if ever, before we have any other product candidate ready for commercialization.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- enroll additional patients in our AUGMENT Study in humans;
- continue our research and preclinical development of OvaTure and other product candidates;
- initiate clinical trials of OvaTure and other product candidates;

- seek approval from the FDA and similar regulatory agencies outside of the United States for our product candidates that require such approval;

- establish a sales, marketing and distribution infrastructure to commercialize AUGMENT and any other product candidates we successfully develop;

- maintain, expand and protect our intellectual property portfolio;

- hire additional scientific, clinical, quality control and management personnel to support our product development and commercialization efforts;

- add operational and financial personnel to handle the public company reporting and other requirements to which we are subject;

- seek to identify additional product candidates that treat infertility; and

- develop, acquire or in-license other products and technologies.

To become and remain profitable, we must continue to develop and commercialize AUGMENT and develop and eventually commercialize other products with significant market potential. This will require us to be successful in a range of challenging activities, including successfully completing our AUGMENT Study in humans, marketing and selling AUGMENT, completing research, preclinical testing and clinical trials of other product candidates, obtaining marketing approval, if required, and manufacturing, marketing and selling those products that we successfully develop. We may never succeed in these activities and, even if we do, may never generate revenues that are significant or large enough to achieve profitability. We have not yet completed the AUGMENT Study or commenced commercialization of AUGMENT and are currently optimizing the design of the development program for our other product candidate, OvaTure. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations.

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We will need substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase significantly in connection with our ongoing and future activities, particularly as we continue with the AUGMENT and OvaTure programs. Assuming we complete our AUGMENT Study on time and with favorable results, and we increase commercial activities on schedule at the scale we expect, we anticipate we will have incurred between $4 million and $5 million in expenses to complete the AUGMENT Study and commence commercial activity in the United States. These estimated expenses for the AUGMENT Study include study site and manufacturing costs, including those associated with technology transfer and process development. We will also incur costs associated with commencing commercialization, including marketing activity and marketing and sales personnel costs. These costs assume that the FDA will regulate AUGMENT as a 361 HCT/P, rather than as a new drug or biologic, and that testing AUGMENT in humans will therefore not require an IND. If the FDA disagrees with our interpretation of the relevant laws and regulations as they apply to AUGMENT, and requires an IND for the AUGMENT Study, these costs would increase substantially. We are planning our initial launch of AUGMENT to include select countries outside the U.S.

In addition, we expect to incur significant expenses with respect to our research and development of OvaTure and other product candidates. The clinical trials we will be required to conduct for these product candidates will be costly. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate some or all of our research and development programs or commercialization efforts.

Assuming we have no revenue from product sales, we expect that our existing cash, cash equivalents and marketable securities will enable us to fund our current operating plan through 2014. Our future capital requirements will depend on many factors, including:

- the timing and results of our AUGMENT Study in humans;
- our ability to successfully commercialize AUGMENT;
- the costs and timing of commercialization activities for AUGMENT, including manufacturing, product sales, marketing and distribution;
- revenue, if any, received from commercial activities of AUGMENT or any other product candidate;
- the scope, progress, results and costs of research, preclinical development, and clinical trials for our product candidates, including OvaTure;
- the regulatory process, including the premarketing and marketing approval requirements, to which some of our product candidates may be subject;
- the costs, timing and outcome of regulatory review of our product candidates that are subject to such review;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- our ability to establish collaborations and partnerships on favorable terms, if at all; and
- the extent to which we develop, acquire or in-license other products and technologies.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time consuming, expensive and uncertain process that takes years to complete. We may never generate the necessary data or results required to obtain necessary marketing approvals or achieve product sales for our product candidates. We do not expect to derive commercial revenues, if any, from AUGMENT until the second half of 2014 at the earliest. We do not expect to derive commercial revenues, if any, from other products for many more years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until the time, if ever, that we can generate substantial product revenues, we plan to finance our cash needs through some combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our existing stockholders will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. Debt financing, if available, 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, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us.

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Risks Related to Research, Development and Commercialization of Our Product Candidates

The science underlying our two principal product candidates, AUGMENT and OvaTure, is based on recent discoveries, and OvaTure has not been tested in humans. We may not be successful in our continuing studies designed to test the safety and efficacy of AUGMENT. In addition, we may not be able to successfully develop OvaTure or other product candidates.

AUGMENT and OvaTure are based on recent scientific discoveries relating to egg precursor cells, and OvaTure has not been tested in humans. As a result, our AUGMENT and OvaTure programs are subject to a higher level of risk than programs based on longer established science that have been the subject of human clinical trials. In December 2012, we commenced our AUGMENT Study in humans to test the safety and efficacy of AUGMENT. The findings of this study, including whether, and by how much, the use of AUGMENT increases the pregnancy and live birth rates of IVF and the safety of this product candidate will impact our ability to commercialize and generate revenues from sales of AUGMENT. If the results of our AUGMENT Study are unfavorable, AUGMENT may not be viable or significant additional time and expense could be required before we are able to market this product candidate.

While one of our scientific founders has successfully conducted laboratory experiments in animals and experiments with human egg precursor cells that form the basis for some aspects of OvaTure, there are significant aspects of OvaTure that will require additional innovation for us to continue its preclinical and clinical development. In addition, successful development of OvaTure depends on our ability to mature human egg precursor cells into fertilizable eggs. Although our scientific founder s research has demonstrated the existence of egg precursor cells in human ovaries, research with respect to egg precursor cells is a new and emerging field. As a result, there is ongoing debate regarding the role of egg precursor cells in human reproduction as well as the ability of egg precursor cells to mature into fertilizable eggs when isolated from ovaries. The recent nature of the scientific discoveries underlying OvaTure, the ongoing debate regarding the ability to mature human egg precursor cells into fertilizable eggs, the need for additional innovation and the absence of information from human clinical trials all increase the risks associated with this product candidate. In any event, we believe that it will be costly and time consuming to develop OvaTure.

If we are unable to complete our AUGMENT Study on our current timeline or if the findings are not favorable, we may postpone or halt our commercial activities. In addition, if we experience delays or difficulties in the enrollment of patients in our AUGMENT Study or future clinical trials for our other product candidates, our ability to commercialize products could be delayed or prevented.

Human studies, like our AUGMENT Study, are expensive, difficult to design and implement and uncertain as to outcome. Success in animal and preclinical studies does not ensure that studies in humans will be successful, and interim or preliminary findings do not necessarily predict final results. In addition, the timing of results from and completion of the study will depend, in part, on our ability to enroll the study on the timeline expected. Enrollment in the study could be delayed for a number of reasons, including the unwillingness of patients to undergo, or physicians to prescribe, an additional surgical procedure in connection with IVF. If enrollment of our AUGMENT Study is delayed, or findings are not favorable, we may postpone or halt our commercial activities, and we may need to expend more cash and other resources than we anticipate to develop AUGMENT. As a result, we might need to delay or abandon development of AUGMENT or our other product candidates. In addition, delays in the time to complete the AUGMENT Study in the United States may impact our ability to commercialize AUGMENT in countries outside the United States.

We may not be able to initiate or continue any future clinical trials for OvaTure or other product candidates for several reasons. For example, if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States, we will not be able to commence clinical studies. Patients who are eligible for future clinical trials may decide to use already approved fertility treatments or to enroll in other clinical trials.

Patient enrollment is affected by other factors including:

- the novelty of the product candidate being tested;
- form of infertility or severity of the condition being treated;
- eligibility criteria for the study in question;
- perceived risks and benefits of the product candidate under study;
- known side effects of the product candidate under study, if any;
- efforts of IVF clinics to facilitate enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

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Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Preclinical testing and clinical trials of OvaTure and any of our other product candidates that require such testing and trials may not be successful. If we are unable to commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed.

We intend to invest a significant portion of our efforts and financial resources in the identification, preclinical development and clinical trials of product candidates that treat infertility. Our ability to generate product revenues will depend heavily on the successful development and eventual commercialization of our product candidates. Unlike AUGMENT, which we believe meets the criteria for regulation as a 361 HCT/P , we expect that the FDA will regulate OvaTure and many of our other product candidates as drugs, biologics or medical devices under the PHSA or FDCA. This means, among other things, that we will not be able to market such products in the United States unless and until we have successfully completed required testing (including clinical testing) and received marketing authorization from the FDA in the form of a NDA or BLA or, for medical devices, a 510(k) clearance or premarket approval application. We have not received approval to market any products from regulatory authorities in any jurisdiction. We have only limited experience in conducting preclinical testing and clinical trials and filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties, including contract research organizations, to assist us in this process.

Prior to initiating clinical trials of OvaTure and other such product candidates, we will need to submit an IND to the FDA based on preclinical, animal and other tests. Upon submitting such an IND, the FDA might determine that the risks involved in OvaTure or our other products are too great to justify proceeding with a clinical study and impose a partial or full clinical hold. They may require us to do significant and costly additional preclinical work before commencing our clinical trials or may not allow us to proceed with clinical trials at all. In addition, an IRB must review and approve any clinical trial before we can commence that trial. The IRB responsible for reviewing any of our clinical trials may decline to grant approval for a variety of reasons, including that they do not believe that patient rights would adequately be protected. OvaTure and our other products rely on new and complex technology that impacts human reproductive systems. Therefore, both the FDA and IRBs may be especially cautious in reviewing and approving our clinical protocols for such products.

If INDs for OvaTure or other product candidates do become effective, we will be required to conduct extensive clinical trials to demonstrate the safety, efficacy, purity and potency of our product candidates in humans. We will need to follow this same process for any future product candidates that are regulated by the FDA as a biologic or new drug. We will need to follow a similar process for any future product candidates that are regulated by the FDA as a medical device.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Either the FDA or an IRB can suspend or terminate our clinical development programs at any time, for a number of reasons, including that further study presents unreasonable risk to human subjects or that the rights of those subjects are not protected.

We may experience numerous unforeseen events during, or as a result of, clinical trials, which could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulators or IRBs may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;

- we may have delays in reaching, or fail to reach agreement on, acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;

- clinical trials of our product candidates may produce negative or inconclusive results, or results subject to varying interpretations, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;

- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate or participants may drop out of our clinical trials at a higher rate than we anticipate;

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- we or our third party contractors may fail to comply with regulatory requirements, such as conducting trials in accordance with current good clinical practices, and our contractors may fail to meet their contractual obligations to us in a timely manner or at all;

- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including discovery that the participants are being exposed to unacceptable health risks;

- the cost of clinical trials of our product candidates may be greater than we anticipate; and

- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate.

- If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns regarding our product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates;

- not obtain marketing approval at all;

- obtain approval for indications or patient populations that are not as broad as we intend or desire;

- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;

- be subject to additional post-marketing testing requirements; or

- have the product removed from the market after obtaining marketing approval.

Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations and changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application. In addition, securing FDA approval requires the submission of information about the product manufacturing process to, and successful inspection of manufacturing facilities by, the FDA.

Our product development costs will also increase if we experience delays in testing or obtaining marketing approvals. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do. Such events could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

Even if clinical trials for our product candidates are completed as planned, the FDA may still conclude that the risks inherent in our product candidates outweigh the demonstrated benefits, and may refuse to grant us marketing authorization. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining, or if we fail to obtain, approval of OvaTure or other product candidates, our ability to generate revenues will be materially impaired and our business will be materially harmed.

If serious adverse or inappropriate side effects are identified during the development of our product candidates or with any procedures with which our product candidates are used, we may need to abandon or limit our development of those product candidates.

None of our product candidates has been proven effective and safe in humans. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or, to the extent required, will receive marketing approval. If our product candidates are associated with undesirable side effects or have characteristics that are unexpected with respect to the patient or the child conceived using our product or product candidates, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In addition, if any of the procedures with which our product candidates are used is determined to be unsafe, we may be required to delay or abandon our product development or commercialization. For example, we expect AUGMENT will be administered as part of the ICSI process. A recent study published in the *New England Journal of Medicine* found that treatment with ICSI was associated with increased rates of birth defects as compared to natural conception. To the extent physicians limit or abandon the use of ICSI or other procedures with which AUGMENT is used, whether as a result of this recent study or otherwise, we may need to delay or abandon our development or commercialization of AUGMENT.

Even if we are able to commercialize any of our product candidates, they may fail to achieve the degree of market acceptance by physicians, patients and others in the medical community necessary for commercial success.

If we are able to commercialize AUGMENT or if any of our other product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients and others in the medical community. For example,

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doctors may continue to rely on current treatments, including fertility drugs and traditional IVF, which are well established in the medical community. In addition, the novel nature of AUGMENT and OvaTure may affect market acceptance by physicians and patients. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of AUGMENT and our other product candidates, if approved for commercial sale, will depend on a number of factors, including:

- efficacy and potential advantages as compared to traditional IVF or other alternative treatments;
- ability to reduce the number of IVF cycles required to achieve a live birth;
- ability to reduce the cost of traditional IVF;
- ability to reduce the incidence of multiple births;
- the willingness of the target population to undergo, and of physicians to prescribe, an additional surgical procedure in connection with IVF;
- convenience and ease of administration as compared to alternative treatments;
- adverse effects on patients or children conceived using our product candidates;
- ability to improve the side effect profile of infertility treatment;
- the willingness of the target population and of physicians to try new therapies based on recent scientific discoveries;
- limitations on the existing infrastructure to support AUGMENT or other product candidates, including adequately trained embryologists and the willingness of IVF clinics to incorporate the process into their current treatment regimen;
- the willingness of patients to pay out of pocket for our products, which, in the case of AUGMENT, will be in addition to the price of a standard IVF procedure;
- any negative publicity or political action related to our or similar products or IVF; and
- the strength of marketing and distribution support.

In addition, our ability to successfully commercialize our products will depend on the continued use and acceptance of IVF, ICSI and fertility treatments generally. In a recent study published in the *New England Journal of Medicine*, treatment with ICSI was associated with an increased risk of birth defects, as compared with natural conception. To the extent these or other studies or findings lead the medical community or patient population to determine that these procedures are unsafe or are otherwise not generally accepted, the market for our products and, therefore, our business would be negatively affected.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our product candidates we may not be successful in commercializing them.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of products for the treatment of infertility. To achieve commercial success for any product, we must either develop a sales and marketing team or outsource these functions to third parties. In anticipation of the commercial launch of AUGMENT in the United States, we plan to recruit appropriate sales and marketing resources. We also plan to recruit appropriate sales and marketing resources for countries outside the United States in which we determine to commercialize AUGMENT on our own, if any. In the future, we may choose to expand the sales force for AUGMENT or other product candidates.

There are risks involved both with establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of AUGMENT or another product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any products ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. We likely will have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively and in compliance with applicable laws.

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We may not be successful in our efforts to identify or discover additional product candidates. If we do identify additional product candidates, we may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

An important element of our strategy is to identify and develop additional product candidates based on our egg precursor cell technology. We may be unable to identify any such product candidates. If we do identify additional candidates, we may not advance such candidates into clinical development for a number of reasons, including:

- evidence that such candidates may have harmful side effects;
- preclinical studies may put into question the efficacy of such candidates;
- we may determine that such candidates are unlikely to achieve marketing approval or market acceptance; or
- such candidates may be too costly to manufacture or market.

Because we have limited financial and managerial resources, we focus on research programs and product candidates based on which candidates we believe have the highest likelihood of success and commercial value. As a result, we may forego or delay pursuit of opportunities with other product candidates 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 may not yield any commercially viable products. For example, the programs we are considering relating to culture media and egg precursor cell banking may not reach commercialization or, if commercialized, may not be successful. 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 when it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We may not be successful in obtaining necessary rights to additional technologies or product candidates, including from our scientific founders, for our development pipeline through acquisitions and in-licenses.

We may be unable to acquire or in-license additional technologies or product candidates from third parties, including our scientific founders, in order to grow our business. A number of more established companies may also pursue strategies to license or acquire product candidates that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we continue to work collaboratively with our scientific founders. These scientists continue to be active in the field of infertility and may develop new product candidates or intellectual property based on their continued research relating to infertility. The rights to new inventions by our scientific founders generally belong to the hospitals and academic institutions at which they are employed and are not subject to license or other rights in our favor. In the event that our scientific founders, or other third party scientists or entities, develop product candidates or intellectual property that we wish to acquire or in-license, we may be unable to negotiate such acquisition or in-license. Our failure to reach an agreement for any applicable product candidate or intellectual property could result in a third party acquiring the related rights and

thereby harm our business.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire relevant product candidates on terms that would allow us to make an appropriate return on our investment.

We expect competition for acquisition and in-licensing product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. If we are unable to successfully obtain rights to suitable product candidates on reasonable terms, or at all, our business, financial condition and prospects for growth could suffer.

We face substantial competition, including from more established infertility treatments, such as traditional IVF, as well as advances in new artificial reproductive technologies, which may result in others discovering, developing or commercializing products before or more successfully than we do.

There are a number of fertility treatments that are generally accepted in the medical and patient communities, including fertility drugs, IUI and IVF. Competition in the infertility market is largely based on pregnancy and live birth rates and side effects of treatment on patients. Accordingly, our success is highly dependent on our ability to develop products that improve pregnancy and live birth rates and reduce risks and side effects, as compared to existing treatments. The ability of any products that we successfully develop to reduce the overall costs associated with IVF also will be an important competitive factor.

Competitors may develop new infertility drugs, ART therapies, devices and techniques that could render obsolete our product candidates. We are not aware of any company or organization developing a specific product that would compete directly with AUGMENT. There are a number of pharmaceutical companies, biotechnology companies, universities and research organizations actively engaged in research and development of products for the treatment of infertility. Some of these products, similar to AUGMENT and OvaTure, are designed to address the shortcomings of IVF. In particular, we are aware of two companies that are

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currently developing products intended to identify high quality embryos for use in IVF. Novocellus Ltd. is developing an embryo viability test, using culture media, to aid in the selection of embryos used in IVF. Auxogyn, Inc. is developing software that analyzes embryo development against cell division timing parameters to help identify the highest quality embryo within a group of embryos. If successfully developed, these products could improve outcomes and alleviate some of the other shortcomings of traditional IVF, thereby decreasing the need for our product candidates. Fertility Focus is developing an embryoscope for the early diagnosis and immediate corrective surgery for the physical causes of infertility. At this time, we cannot evaluate how our products, if successfully developed and commercialized, would compare technologically, clinically or commercially to any other potential products being developed or to be marketed by competitors. There can be no assurance that we will be able to compete effectively.

Our competitors may develop and commercialize new technologies before we do, allowing them to offer products, services or solutions that are superior to those that we may offer or which establish market positions before the time, if any, at which we are able to bring products to the market. Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than we may be in developing, commercializing and achieving widespread market acceptance. Our competitors products may be safer, more effective or more effectively marketed and sold, than any treatment we may commercialize and may render our product candidates obsolete or non-competitive before we can recover the expenses of developing and commercializing any of our product candidates. We anticipate that we will face intense and increasing competition as new treatments enter the market and advanced technologies become available.

We could be subject to negative publicity, political action and additional regulation because of the nature of our products. These factors could increase our development and commercialization costs.

Our products are based on innovative science regarding eggs, embryos and fertilization. These can be controversial subjects and, as a result, we could be subject to adverse publicity, political reaction and regulation, as well as changes to the laws and regulations affecting our product candidates. This may result in our incurring costs beyond what we anticipate in order to develop and commercialize our product candidates or may make it impossible to develop our product candidates at all. In addition, some states are considering adopting legislation defining when personhood begins. To the extent adopted, this legislation could limit, restrict or prohibit the use of IVF, which would have a negative effect on our ability to develop and sell our product candidates and, as a result, on our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human studies and clinical trials and will face an even greater risk if we commercialize AUGMENT or any other products that we may develop. Product liability claims involving our activities may be made for significant amounts because our product candidates involve mothers and children. For example, it is possible that we will be subject to product liability claims that assert that our product candidates or products have caused birth defects in children or that assert that such defects are inheritable. In light of the nature of our planned activities, these claims could be made many years into the future based on effects that were not observed or observable at the time of birth. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;

- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- the diversion of management s resources; and
- the inability to commercialize any products that we may develop.

We obtained product liability insurance coverage when we initiated our AUGMENT Study. We will need to maintain product liability insurance coverage during our AUGMENT Study in humans and clinical trials for our other product candidates. Such insurance is increasingly expensive and difficult to procure. In the future, such insurance may not be available to us at all, may only be available at a very high cost and, if available, may not be adequate to cover all liabilities that we may incur. In addition, we may need to increase

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our insurance coverage in connection with the commercialization of AUGMENT or other product candidates. If we are not able to obtain and maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise, our business could be harmed, possibly materially.

Procedures such as IVF, as well as companies that manufacture and store cells and tissues, are the subject of standards and recommendations by national non-governmental bodies. Failure to comply with these standards could harm our commercial prospects or subject us to negative media attention or government sanctions.

Some national organizations set voluntary guidelines for procedures like IVF and for the manufacture and storage of human cells and tissues. The American Society for Reproductive Medicine, or ASRM, for example, has issued recommendations on the minimum standards that ART practices should employ, including minimum qualifications of personnel and record keeping and informed consent practices. ASRM also has issued guidelines on the number of embryos that should be transferred at a single time through IVF. Similarly, the American Congress of Obstetricians and Gynecologists sets forth guidelines on numerous topics such as the circumstances in which embryos can be used for research purposes and the use of innovative medical procedures in clinical practice. Although voluntary, subject to exceptions discussed below, if we, or third parties that we work with, including IVF clinics, fail to comply with these standards, our commercial prospects could be harmed because patients may prefer to use the services and products of companies that meet these voluntary standards. Similarly, physicians or IVF clinics may be less likely to endorse or use procedures or products that would violate such standards. In addition, failure to meet the standards could subject us to negative media attention. Moreover, noncompliance with these professional organization standards could subject us to compliance risks in states that have incorporated the standards into state law. For example, the state of Maryland has incorporated certain portions of the American Association of Tissue Banks Standards for Tissue Banking into its regulations. Failure to comply with certain standards could, therefore, amount to a violation of state law to the extent we operate in a state that adopts a voluntary guideline into its regulations.

Risks Related to Regulatory Approval of Our Product Candidates and Other Regulatory Matters

Our current business plan assumes that the FDA will regulate AUGMENT as a 361 HCT/P rather than as a new drug or biologic and, therefore, AUGMENT will not be subject to premarket review and approval. If the FDA disagrees with our interpretation of the applicable regulations, disagrees with our characterization of the AUGMENT procedure or changes its position with respect to such rules and regulations, we may not be able to commercialize AUGMENT on the timeline or with the resources we expect, if at all. We could also be forced to halt human studies, remove the product from the market or be subject to substantial fines or other civil or criminal sanctions.

The FDA regulates HCT/Ps, such as AUGMENT, under a two-tiered framework. Certain higher risk HCT/Ps are regulated as new drugs, biologics or medical devices. Manufacturers of new drugs, biologics and some medical devices must complete extensive clinical trials, which must be conducted pursuant to an effective IND or investigational device exemption. The FDA must review and approve a BLA or NDA before a new drug or biologic may be marketed, and in some cases must approve a premarket approval application for medical devices.

By contrast, the FDA exempts certain lower risk HCT/Ps from these requirements if they meet certain specified criteria. Such products frequently are referred to as 361 HCT/Ps, because the FDA regulates them under the authority given to it under section 361 of the PHSA to create regulations to control the spread of communicable diseases. We believe that AUGMENT meets the criteria for regulation as a 361 HCT/P rather than as a new drug or biologic and, therefore, that AUGMENT will not be subject to the requirement for an IND or FDA premarket review and approval. Thus, our current financial and business plans assume that we will not need to seek or obtain FDA approval for AUGMENT. Rather, we will have to comply with the requirements for 361 HCT/Ps set forth in FDA regulations and develop adequate substantiation to support marketing claims we make for the AUGMENT procedure.

The TRG is a body within the FDA designed to provide formal opinions regarding whether a particular product will be regulated as a 361 HCT/P. Product manufacturers are not required to consult with the TRG and instead can market their products based on their own conclusion that the product meets the 361 HCT/P criteria.

We have not consulted the TRG. We have, however, been contacted by the FDA regarding the AUGMENT Study, and a number of other matters relating to AUGMENT, including whether it qualifies for regulation as a 361 HCT/P. We continue to believe that AUGMENT qualifies as a 361 HCT/P; however, the FDA could disagree with our conclusion.

The regulatory pathway for cell and tissue-based products is subject to significant uncertainty. The FDA s criteria for regulation as a 361 HCT/P are complex, and the FDA has provided little guidance on the meaning of terms used in the criteria, such as minimal manipulation, homologous, or combination of the cells and tissues with another article. In addition, AUGMENT uses new technology that would present a matter of first impression for the FDA in determining whether to require premarket authorization. Further, AUGMENT may receive a high degree of scrutiny from the FDA due to its use as an aid to reproduction. The FDA or

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Congress could change the relevant criteria for determining which products qualify as 361 HCT/Ps or the regulatory requirements for HCT/Ps.

The courts may also interpret those criteria and requirements in unexpected ways. For example, in United States v. Regenerative Sciences LLC, the United States District Court for the District of Columbia recently rejected a company s argument that the Regenexx Procedure, which involves the use of stem cells for the treatment of various orthopedic conditions, was exempt from regulation by the FDA because the procedure constitutes the practice of medicine. The court also held that the procedure does not qualify for regulation as a 361 HCT/P because it involves more than minimal manipulation of the cells. The court s finding turned on the fact that the Regenexx Procedure involves cell culture and expansion, which changes the biological characteristics of the cells. We think the AUGMENT procedure is distinguishable from the Regenexx Procedure because AUGMENT does not involve cell cultures or cell expansion. Nonetheless, this case suggests that courts may take a narrow view of what constitutes minimal manipulation. Importantly, the court also noted the longstanding principle that the FDA s decisions on scientific matters, including the agency s conclusion that the procedure involves more than minimal manipulation, are entitled to substantial deference. This means that if the FDA disagrees with our conclusion that AUGMENT should be regulated as a 361 HCT/P, and not as a new biologic or drug, it may be very difficult to challenge the agency s position in court.

If the FDA determines that AUGMENT is not a 361 HCT/P, regulates it as a new drug or biologic and, therefore, requires premarket review, we may be required to halt our AUGMENT Study or other uses of AUGMENT in humans and conduct a more time-consuming and expensive clinical trial program for this product candidate. We may also be required to submit an IND and an NDA or BLA to secure marketing authorization. The submission of an IND and a BLA or NDA would require us to compile significant amounts of data related to the AUGMENT process, as well as data from preclinical and clinical testing. If, at the time the FDA determines that AUGMENT is not a 361 HCT/P, we are already marketing the product, we may be required to withdraw it from the market pending submission, review and FDA approval of a BLA or NDA. We cannot guarantee that we would ever be able to secure such approval. We could also be subject to a warning letter, substantial fines and other civil or criminal penalties. As a result, our business could be materially harmed.

Even if the FDA regulates AUGMENT as a 361 HCT/P, we must still generate adequate substantiation for any claims made in our marketing of AUGMENT. Failure to establish such adequate substantiation in the opinion of federal or state authorities could substantially impair our ability to generate revenue.

Although as a 361 HCT/P we may not need to submit AUGMENT to the FDA for preapproval, we still must generate adequate substantiation for claims we make in our marketing materials. Both the FTC and the states retain jurisdiction over the marketing of products in commerce and require a reasonable basis for claims made in marketing materials. Through our AUGMENT Study in humans and other endeavors, we intend to generate such adequate substantiation for any claims we make about the AUGMENT procedure. If, however, after we commence marketing of AUGMENT, the FTC or one or more states conclude that we lack adequate substantiation for our claims, we may be subject to significant penalties or may be forced to alter our marketing of AUGMENT in one or more jurisdictions. Any of this could materially harm our business. In addition, if our promotion of AUGMENT suggests that the HCT/P is not intended for homologous use, the FDA might consider the product to be a new drug or biologic. We will therefore be limited in the promotional claims that we could make about AUGMENT.

We may not be able to continue our AUGMENT Study as planned.

We believe that AUGMENT meets the criteria for regulation as a 361 HCT/P and, therefore, will not require an IND for our AUGMENT Study in humans. However, the FDA could disagree with our conclusion and require us to submit an IND. Moreover, even if our study does not require an IND, it will still be subject to various requirements designed to protect the safety of study participants. For example, we have received IRB approval and monitoring of our AUGMENT Study. The IRB could, however, require us to alter our program. Such changes could materially

impact the time and costs required to complete the program.

Numerous states place restrictions on the operation of facilities and laboratories that recover, test, process, manufacture, store or dispose of certain cells and tissues. If we do not comply with such state regulations, as well as potential local regulations, we could be subject to significant sanctions.

Various states, including New York, California, Florida, Illinois, Maryland, Texas, Massachusetts and others, impose requirements on facilities and laboratories that recover, test, process, manufacture, store or dispose of certain cells and tissues. These requirements can have significant geographic reach. In Maryland, for example, the permit requirements applicable to tissue banks, including reproductive tissue banks, apply not only to tissue banks located in Maryland, but also those tissue banks located outside of the state that are represented or serviced in Maryland. In some cases, the requirements imposed by states, such as record keeping and testing requirements, may be more stringent than those imposed by the FDA. Failure to comply with these state requirements could subject us to significant sanctions.

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We will not be able to sell any product that is regulated as a medical device without obtaining and maintaining necessary regulatory clearances or approvals.

To market any products that are regulated as medical devices, or that require the use of a new medical device, such as the innovative culture media solution that we are planning to develop, we will need to seek approval or clearance from the FDA, either through the premarket approval process or the 510(k) clearance process. We currently expect to be able to rely on the 510(k) clearance process, as opposed to the premarket approval process, for some of our medical device product candidates. However, it is difficult to predict whether the FDA will allow us to use the 510(k) pathway or require us to use the premarket approval process. We cannot guarantee that we will be able to obtain clearance or approval of these medical devices through either pathway. In addition, even if the FDA permits us to use the 510(k) pathway, the requirements to bring a product to market through this process may be significantly more resource intensive than we currently expect. The FDA has announced that it intends to make changes to the 510(k) process, and these changes, or any other changes related to FDA s regulation of medical devices, could have an adverse effect on our ability to gain regulatory clearance for, and to commercialize, our product candidates. In addition, any modifications to medical devices that we successfully bring to market, if any, may require new regulatory clearances or premarket approvals. Marketing a medical device without the necessary clearance or approval could result in a warning letter, fines, injunctions, product seizures or other civil or criminal penalties. Delays in our receipt of regulatory clearance or approval will cause delays in our ability to sell our products, which will have a negative effect on our ability to generate and grow revenues.

Failure to obtain required marketing approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In order to market and sell our products in the EU and many other jurisdictions, we or our third party collaborators may need to obtain separate marketing approvals and will need to comply with numerous and varying regulatory requirements. The approval process varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally is subject to all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, a product must be approved for reimbursement before the product can be approved for sale in that country. We or these third parties may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA for marketing in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

In the EU, for example, our products could be regulated as medicinal products, as advanced therapy medicinal products, as medical devices or as human tissues and cells intended for human applications. Products regulated as advanced therapy medicinal products may only be placed on the market in the EU once they have been granted a marketing authorization by the European Commission. Securing a marketing authorization from the European Commission requires the submission of extensive preclinical and clinical data and supporting information, including information about the manufacturing process, to the EMA to establish the product candidate s safety, efficacy and quality. Following review of the marketing authorization application the EMA will issue an opinion, which the European Commission will take into account when deciding whether or not to grant a marketing authorization. Products regulated as medical devices in the EU are not subject to premarket review and approval by regulatory authorities. However, before placing the product on the market in the EU the manufacturer must demonstrate that the product meets certain essential requirements set out in applicable laws. For lower risk devices, the manufacturer may self-declare conformity to the essential requirements and apply the CE mark to the device. All other devices must undergo a conformity assessment procedure by a notified body, which is a third party licensed by regulatory authorities to perform such assessments. If the notified body agrees that the essential requirements have been met, it will issue a CE certificate, which allows the manufacturer to draw up a declaration of conformity and apply the CE mark to the device. Once a medical device has been CE marked it may be marketed throughout the EU.

Products regulated as human tissues and cells for human applications that do not fall within the definition of an advanced therapy medicinal product or a medical device are not generally subject to premarket review and approval by regulatory authorities. However, the establishments that process and use such human tissues and cells must be licensed and are subject to various quality system and adverse event reporting requirements. We believe that the AUGMENT procedure should be subject to this general regimen for human cells and tissues, but regulatory authorities in the EU could disagree with our conclusion and determine that the procedure involves sufficient manipulation of the cells to bring the product within the scope of the rules governing advanced therapy medicinal products. The relevant criteria for determining which products qualify as advanced therapy medicinal products could also change. If the European Commission or other regulatory authority determines that AUGMENT is an advanced therapy medicinal product and, therefore, requires premarket review, we may be required to halt any on-going studies or other uses in humans and conduct a more time consuming and expensive clinical trial program for this product candidate and may be unable to file for or obtain the necessary approvals to commercialize AUGMENT.

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While we believe EU marketing authorization is not required, medical treatments and processes, such as IVF, are regulated at the national level in the EU. Such national regulations may restrict the extent to which the eggs used in IVF treatments may be manipulated. In addition, certain other countries outside the EU and United States may have regulations that require us to obtain permission prior to commercializing AUGMENT.

Even if we obtain marketing approval in international jurisdictions, economic, political and other risks associated with foreign operations could adversely affect our international sales.

If we succeed with our international commercialization strategy, then our business will be subject to risks associated with doing business internationally. For example, our future results of operations could be harmed by a variety of factors, including:

- changes in foreign currency exchange rates;
- changes in a country s or region s political or economic conditions, particularly in developing or emerging markets;
- trade protection measures and import or export licensing requirements;
- differing business practices associated with foreign operations;
- difficulty in staffing and managing widespread operations, including compliance with labor laws and changes in those laws;
- differing protection of intellectual property and changes in that protection; and
- differing regulatory requirements and changes in those requirements.

We do not currently have an international infrastructure and have no experience in conducting foreign operations. Establishing commercial activities and complying with laws in foreign jurisdictions may be costly and could disrupt our operations.

Even if we successfully launch AUGMENT, it will be subject to ongoing regulation. We could be subject to significant penalties if we fail to comply with these requirements, and we may be unable to commercialize our products.

Even if the FDA allows AUGMENT or any other product candidate of ours to be marketed as a 361 HCT/P and, therefore, without an NDA or BLA, we will still be subject to numerous post-market requirements, including those related to registration and listing, record keeping, labeling, current good tissue practices, or cGTPs, donor eligibility and other activities. HCT/Ps that do not meet the definition of a 361 HCT/P and, therefore, are approved via an NDA or BLA, are also subject to these ongoing obligations. If we fail to comply with these requirements, we could be subject to warning letters, product seizures, injunctions or civil and criminal penalties. We are currently relying on a third party cGTP-compliant facility to conduct the various steps involved in the AUGMENT process, including the purification of the woman s mitochondria from the tissue biopsy. In the future, we may establish our own processing facility, which would need to be cGTP compliant. Any failure by us or the third party facility on which we rely to maintain cGTP compliance could require remedial action, such as product recalls and

delays in distribution and sales of AUGMENT and any other products that we develop, as well as enforcement actions.

Moreover, even if the FDA allows AUGMENT or any other product candidate to be marketed without premarket approval, the FDA could still seek to withdraw the product from the market for a variety of reasons, including if the agency develops concerns regarding the safety or efficacy of the product or the product s manufacturing process.

OvaTure and any other product candidates for which we obtain marketing approval are subject to continuing regulation after approval. We may be subject to significant penalties if we fail to comply with these requirements.

Any product candidate for which we obtain marketing approval or clearance will be subject to continuing regulation by the FDA and other regulatory authorities. For example, such products will be subject to requirements relating to submission of safety and other post-marketing information and reports, registration and listing, manufacturing, packaging, quality control, storage, distribution, quality assurance and corresponding maintenance of records and documents, labeling, advertising and promotional activities, distribution of samples to physicians and recordkeeping. Even if marketing approval or clearance of a product candidate is granted, the approval or clearance may be subject to limitations on the uses for which the product may be marketed, be subject to restrictions on distribution or use through a risk evaluation and mitigation strategy, or contain requirements for costly post-marketing testing to further evaluate the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs, biologics and medical devices to ensure such products are marketed only for the approved indications or cleared uses and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers communications regarding off-label use and if we market our products other than for their approved indications, we may be subject to enforcement action for off-label marketing.

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In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing clinical trials;
- warning or untitled letters from the FDA;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications;
- recall of products;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions; or
- the imposition of civil or criminal penalties.

It is unlikely that third party payors will cover or reimburse for AUGMENT or other, future products and services, and many patients may be unable to afford them.

Many third party payors, both in the United States and the EU, including national health services or government funded insurance programs as well as private payors, place significant restrictions on coverage and reimbursement for IVF and other ART procedures. Those restrictions may include limits on the types of procedures covered, limits on the number of procedures covered and overall annual or lifetime dollar limits on reimbursement for IVF and other ART procedures. As a result, we believe very few third party payors, either in the United States or the EU, will reimburse for AUGMENT or likely our other future products and services. Thus, it is likely that IVF clinics and physicians will be able to use AUGMENT and our other products and services in the treatment of a patient only if the patient can afford and is willing to pay out-of-pocket. The cost of AUGMENT and our other future products and services may be beyond the means of many patients. This may limit the size of the market for AUGMENT or our future products and services and, thereby, limit our future revenues.

Even in those limited situations in which government or private payors may cover AUGMENT or other, future products and services, cost containment pressures may later cause these third party payors to adopt strategies designed to limit the amount of reimbursement paid to IVF clinics and physicians, including but not limited to the following:

- reducing reimbursement rates;
- challenging the prices charged for medical products or services;
- further limiting products and services covered;
- challenging whether products or services are medically necessary;
- taking measures to limit utilization of products and services;
- negotiating prospective or discounted contract pricing;
- adopting capitation strategies; and
- seeking competitive bids.

Additionally, in those limited situations where ART procedures such as IVF are available to disabled patients of childbearing age enrolled in federal healthcare programs, such as Medicare, the covered services and products may be subject to changes in coverage and reimbursement rules and procedures, including retroactive rate adjustments. These contingencies could even further decrease the range of products and services covered by such programs or the reimbursement rates paid directly or indirectly for such products and services. Such changes could further limit our ability to sell our products, which may have a material adverse effect on our revenues.

In March 2010, Congress enacted sweeping healthcare reform legislation known as the Affordable Care Act. The Affordable Care Act will substantially change the way that healthcare is financed by both governmental and private insurers and significantly affect the delivery and financing of healthcare in the United States. The Affordable Care Act contains provisions that, among other things, govern enrollment in federal healthcare programs, effect reimbursement changes, encourage use of comparative effectiveness research in healthcare decision making and enhance fraud and abuse requirements and enforcement. The Affordable Care Act imposes a significant annual fee on companies that manufacture or import branded prescription drug products, which could include products such as OvaTure, if the FDA regulates it as a biologic. The fee, which is not deductible for federal income tax purposes, is based on the manufacturer s market share of sales of branded drugs and biologics, excluding orphan drugs, to, or pursuant to coverage under,

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specified U.S. government programs. In addition, the new law subjects most medical devices to a 2.3% excise tax, beginning on January 1, 2013. The implementation of the Affordable Care Act may have a material adverse effect on our results of operations and financial condition.

The reimbursement process for products and procedures outside the United States generally is subject to all of the risks associated with reimbursement in the United States, including the risk that it is unlikely that third party payors will cover or reimburse AUGMENT or other, future products and services. Many national health services and third party payors in the EU already place coverage and reimbursement limits on ART procedures, including IVF, and may impose even greater limits in the future. In many EU member states medicinal products and medical devices are subject to formal pricing and reimbursement approvals before they can be reimbursed by national health services or government-funded insurance schemes. Reimbursement may be conditional on the agreement by the seller not to sell the product above a fixed price in that country, or the national authority may unilaterally establish a reimbursement price in connection with the inclusion of the product on a list of reimbursable products.

The likelihood that many third party payors will refuse to cover and reimburse for AUGMENT and our future products and services and that many patients will be unable to afford to pay for them out of pocket may reduce the demand for, or the price of, AUGMENT and other future products and services, which would have a material adverse effect on our revenues. Additional legislation or regulation relating to the healthcare industry or third party coverage and reimbursement may be enacted in the future, and could adversely affect the revenues generated from the sale of our products.

Several states have enacted legislation that may hamper the ability of IVF clinics and physicians to pass through the cost of our products to patients or third party payors.

Several states, including California and New York, require direct billing of laboratory or pathology services, prohibit physicians from marking up the cost of laboratory or pathology services when they pass these costs on to patients or other payors or require that physicians disclose to patients what they actually paid to obtain laboratory or pathology services. Additionally, the federal government has enacted regulations limiting the Medicare reimbursement available to physicians who contract out the technical component of certain laboratory and pathology procedures.

To the extent that AUGMENT or possibly other, future products or services are treated as laboratory or pathology services for purposes of reimbursement, these laws may make it difficult for us to market those products and services to IVF clinics and physicians in some states and may also require us to restructure our business model before we can expand into certain markets. To the extent that our IVF clinic and physician customer base anticipates seeking Medicare reimbursement, these laws may require a comprehensive restructuring of our business model, and therefore adversely impact our ability to market our products. Any additional legislation or regulation in this area could also adversely affect our ability to market our products.

Even though we anticipate very limited third party coverage and reimbursement for AUGMENT and our future products and services, our future arrangements with third party payors and IVF clinics and physicians may be subject to federal and state fraud and abuse laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Even though we anticipate very limited third party coverage and reimbursement, including from federal healthcare programs, for AUGMENT and possibly other, future products and services, our future arrangements with third party payors and IVF clinics and physicians may expose us to broadly applicable fraud and abuse laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute AUGMENT and possibly other, future products and services for which we obtain marketing approval. Restrictions under federal and state fraud and abuse laws and regulations that may be applicable to our business include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- the federal Stark law prohibits physicians from referring patients to hospitals, laboratories, and other types of entities in which they or their immediate family members have a financial interest, if the referral is for a select list of Medicare or Medicaid-covered services, including most clinical laboratory services, and also prohibits entities that furnish the covered services subsequent to a prohibited referral from billing Medicare or Medicaid for the services provided and from receiving payment from a federal healthcare program for those services;

- the federal False Claims Act imposes civil penalties, often through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for

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payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes criminal and civil liability for failure to safeguard the privacy, security and transmission of individually identifiable health information and for executing a scheme to defraud any federal healthcare program;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in any matter within the jurisdiction of the executive, legislative, or judicial branch of the U.S. government, including in connection with the delivery of or payment for federally reimbursed healthcare benefits, items or services;

- the federal transparency requirements under the sunshine provisions of the Affordable Care Act require manufacturers of drugs, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to physician payments and other transfers of value and physician ownership and investment interests;

- analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures; and

- analogous foreign laws and regulations, such as anti-bribery laws and laws governing the promotion of medicinal products or medical devices, may apply to sales or marketing arrangements and interactions with physicians in countries outside the United States.

Efforts to ensure that our business arrangements with third parties will comply with applicable fraud and abuse laws and regulations will involve substantial costs. It is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the IVF clinics or physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even the assertion of a violation under any of these provisions could have a material adverse effect on our financial condition and results of operations. Any such assertion would likely trigger an investigation of our business or executives that could cause us to incur substantial costs and result in significant liabilities or penalties, as well as damage to our reputation.

We may have obligations under our contracts with IVF clinics and physicians or other healthcare providers to protect the privacy of patient health information.

In the course of performing our business, we will obtain, from time to time, confidential patient health information. For example, we may learn patient names and be exposed to confidential patient health information when we provide training on AUGMENT and possibly other, future products and services to the staff at IVF clinics and physicians offices. United States federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information and privacy and security rules under HIPAA. At this time, we are not a HIPAA covered entity. However, our current and future business associate or other confidentiality agreements with covered entities contain commitments to protect the privacy and security of patients health information and, in some instances, may require us to indemnify the covered entity for any claim, liability, damage, cost or expense arising out of or in connection with a breach of the agreement by us. If we were to violate one of these agreements, we could lose customers and be exposed to liability or our reputation and business could be

harmed. In addition, the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted in February 2009, expands the HIPAA privacy and security rules, including imposing many of the requirements of those rules directly on business associates and making business associates directly subject to HIPAA civil and criminal enforcement provisions and associated penalties. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements. Our failure to comply may result in criminal and civil liability.

Other federal and state laws apply to the use and disclosure of health information, as well as certain financial information, which could affect the manner in which we conduct our business. Such laws are not necessarily preempted by HIPAA, in particular those laws that afford greater protection to the individual than does HIPAA or cover different subject matter. Such state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

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In the member states of the EU and many other countries, we will be subject to similar or more stringent data privacy laws, such as those implementing the European Data Protection Directive 94/46/EC, that require us to protect all individually identifiable information and restrict the use, disclosure and onward transfer of that information. Such national laws typically have their own civil or criminal enforcement provisions and associated penalties. We may incur costs in complying with the applicable privacy and security requirements, which may include registration with the national data protection authorities.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous 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 in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to the Manufacturing of Our Product Candidates

We have entered into agreement with a third party for the manufacture of AUGMENT and expect to rely on third parties for the manufacture of our other product candidates for preclinical testing, clinical trials and 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 because we have limited control of third parties activities, including manufacturing capacity and costs and regulatory compliance.

We do not have any processing or manufacturing facilities or personnel. In July 2013, we entered into a master services agreement with a new third party manufacturer to provide services for the manufacture of AUGMENT to replace our existing contract manufacturer, whose contract with us expires in August 2013. While we believe that our new third party has the capability to undertake the manufacture of AUGMENT in

accordance with all applicable rules and regulations, there can be no assurance that it will be able to do so successfully. We do not have internal or external capabilities to manufacture AUGMENT or OvaTure or any other product candidate.

Reliance on third party manufacturers and laboratories, entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing or service agreement by the third party; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

We expect to rely on third party manufacturers or third party collaborators for the manufacture of our other product candidates for preclinical testing, clinical trials and for commercial supply. We may be unable to establish any agreements with third party manufacturers or to do so on acceptable terms.

Third party manufacturers and laboratories may not be able to comply with cGTP or current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Any performance failure on the part of our existing or future manufacturers and service providers, could delay clinical development or marketing approval or adversely affect or impede commercial sales. Our failure, or the failure of our third party manufacturers and service providers, to comply with applicable regulations could also result in sanctions being imposed on us, including fines, injunctions, civil penalties, suspension or withdrawal

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of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and harm our business and results of operations.

We may compete with other companies for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGTP and cGMP regulations and that might be capable of manufacturing for us. It is possible that some of these manufacturers have agreements with our competitors that limit or restrict their ability to contract with us, further narrowing the number of manufacturers that are available to us.

We do not currently have arrangements in place for redundant supply or a second manufacturing source for AUGMENT. If our current contract manufacturer cannot perform as agreed, we may be required to find a replacement. Although we believe that there are other potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. We are pursuing a second potential manufacturing source for AUGMENT.

Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to commercialize AUGMENT or any future product candidates that we seek to market on a timely and competitive basis.

We do not currently have a manufacturer for AUGMENT outside of the United States. If our current third party is unable to supply AUGMENT for countries outside the United States, we will need to contract with third party manufacturers that comply with cGTP regulations to supply AUGMENT in EU countries and other jurisdictions in which we decide to commercialize AUGMENT, if any. Although we believe there are other manufacturers who could manufacture our product candidates outside the United States, we may incur added costs and delays in identifying and qualifying a non-United States manufacturer.

Providing AUGMENT to patients in jurisdictions outside the United States requires coordination internally among our employees and externally with physicians, IVF clinics, regulatory authorities and third party suppliers and carriers. For example, a patient s physician or clinical site will need to coordinate with us to ship a patient s ovarian tissue biopsy to the cGTP-compliant facility responsible for the next steps in the AUGMENT process, and we will need to coordinate with them to ship isolated cellular components from the patient s processed tissue back to them. Such coordination involves a number of risks that may lead to failures or delays in processing our AUGMENT product. If we are unable to coordinate appropriately, we may encounter delays, incur additional costs or adversely affect our ability to commercialize AUGMENT.

We intend to improve the efficiency and reduce the cost of our current AUGMENT process prior to commercialization. If we fail to do so, we may not continue commercial activities or generate significant revenues, and the profitability of our planned operations could be adversely affected.

We continue to enhance the process for AUGMENT. As a result, while we are not able to project the likely AUGMENT costs, we believe that we will need to significantly reduce AUGMENT costs in order to achieve commercial success. We are actively working on initiatives to achieve these cost savings. However, there can be no assurance that these initiatives will be successful. If we are not successful in reducing AUGMENT costs, we may not be able to continue commercial activities on schedule, if at all, AUGMENT revenues may be lower than we expect and the profitability of AUGMENT sales could be adversely affected, possibly materially.

In the future, we may build and equip a cGTP-compliant facility for the processing of AUGMENT in the United States. Constructing and equipping such a facility in compliance with regulatory requirements will be time consuming and expensive.

In the future, we may lease, build and equip a cGTP-compliant facility for the processing of AUGMENT in the United States. We believe that such a facility may be important to our ability to meet demand for AUGMENT and to process AUGMENT on a cost-effective basis. The leasing, build-out and equipping of this facility will require substantial capital expenditures. In addition, it will be costly and time consuming to recruit necessary additional personnel for the operation of the facility. We do not currently have funding available for any of these purposes. If we are unable to successfully construct and equip a commercial manufacturing facility in compliance with regulatory requirements, or hire additional necessary personnel appropriately, our revenues from AUGMENT, and the profitability of such revenues, may be adversely affected.

Lack of coordination internally among our employees and externally with physicians, IVF clinics and third party suppliers and carriers could result in processing and manufacturing difficulties, regulatory enforcement actions, disruptions or delays and cause us to have insufficient product to meet our expected AUGMENT Study requirements or potential commercial requirements.

Providing AUGMENT to patients requires coordination internally among our employees and externally with physicians, IVF clinics and third party suppliers and carriers. For example, a patient s physician or clinical site will need to coordinate with us to ship a

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patient s ovarian tissue biopsy to the cGTP-compliant facility responsible for the next steps in the AUGMENT process, and we will need to coordinate with them to ship the patient s egg precursor cells, or the patient s mitochondria from the egg precursor cells, to them. Such coordination involves a number of risks that may lead to failures or delays in processing our AUGMENT product, including:

- difficulties in the timely shipping of patient-specific materials to us or in the shipping of our product candidates to the treating physicians due to errors by third party carriers, transportation restrictions or delays or other reasons;

- destruction of, or damage to, patient-specific materials or our product candidates during the shipping process due to improper handling by third party carriers, hospitals, physicians or us;

- destruction of, or damage to, patient-specific materials during any of the tissue or cell processing steps required for egg precursor cell isolation and selection of the patient specific mitochondria;

- destruction of, or damage to, patient-specific materials or our product candidates during storage at our facilities;

- failure to maintain precise patient records to ensure the chain of custody, meaning the patient ovarian tissue biopsy creates the mitochondria sample that is delivered back to the IVF clinic and used in the same patient;

- destruction of, or damage to, patient-specific materials or our product candidates stored at clinical and future commercial sites due to improper handling or holding by clinicians, hospitals or physicians;

- failure to ensure adequate quality control and assurances in the AUGMENT process as we increase production quantities; and

- failure to establish additional manufacturing.

If we are unable to coordinate appropriately, we may encounter delays or additional costs in achieving our clinical and commercialization objectives. We, or third parties, could face regulatory action as a result of the failure to comply with cGTPs or other applicable rules. Some or all of these risks may also be applicable to OvaTure and any other future product candidates.

Risks Related to Our Dependence on Third Parties

We rely on a third party to conduct our AUGMENT Study and intend to rely on third parties to conduct our clinical trials for other product candidates. Such third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials.

We are relying on a third party clinical research organization to conduct our AUGMENT Study and intend to rely on third parties, such as clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct clinical trials for our other product candidates. Our reliance on these third parties for clinical development activities will reduce our control over these activities.

We will remain responsible for ensuring that our AUGMENT Study and each of our future clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA will require us to comply with GCPs with respect to any clinical trials conducted in connection with a submission to the FDA, including an IND, and will require that we record and report clinical trial results to assure that data and reported results are credible and accurate and that the rights and safety are protected. We will also be required to register ongoing FDA-regulated clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors, and could devote more of their resources to such other entities at the expense of expending sufficient resources on our clinical development activities.

We expect to depend on collaborations with third parties for the development and commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We currently intend to commercialize AUGMENT ourselves in the United States and certain EU member states and to collaborate with third parties to commercialize AUGMENT and any future product candidates in other international markets. In addition, we may seek partners for further development and commercialization of our other product candidates. These collaborations could take the form of license, distribution, sales representative, joint venture, sponsored research or other arrangements with pharmaceutical and biotechnology companies, other commercial entities and academic and other institutions.

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If we do enter into any such arrangements with third parties, we will likely have limited control over the amount and timing of resources that such collaborators dedicate to the development or commercialization of our product candidates. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. Our ability to generate revenues from these arrangements will depend on, among other things, our collaborators successful performance of the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and could devote fewer resources to our product candidates than we expect them to;

- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of our product or products;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator s strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;

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

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;

- 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 proprietary information;

- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management s attention and resources; and

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

If we are not able to establish collaborations, we may have to alter our development and commercialization plans.

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of some of our product candidates. For example, we currently intend to seek to collaborate with third parties to commercialize AUGMENT and other product candidates we successfully develop in certain EU member states and other parts of the world.

We face significant competition in seeking appropriate collaborators. Whether we 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 evaluation of a number of factors. Those factors may include the design or results of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States of our product candidate, the potential market for such product candidate, the costs and complexities of manufacturing and delivering the product candidate to patients, the potential and relative cost of competing products, 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 or conditions 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. We may also be restricted under existing license agreements from entering into agreements on certain terms with potential collaborators. In addition, there have been a significant number of recent business combinations among pharmaceutical and biotechnology companies that have resulted in a reduced number of potential future collaborators. Collaborations are complex and time consuming to negotiate and document. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

If we are not able to obtain a collaborator for a particular program, we may have to curtail the development of such program or of one or more of our other development programs, delay the potential commercialization of such program or reduce the scope of any sales or marketing activities for the program or increase our expenditures and undertake development or commercialization activities for the program at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring these product candidates to market and generate product revenue.

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Risks Related to Our Intellectual Property

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

We have an exclusive license from MGH with respect to the intellectual property that forms the basis of our business. Our existing MGH license agreement and another agreement granting us rights impose, and we expect that future license agreements will impose, various obligations on us, including diligence, milestone payments, royalty payments, insurance and other obligations, as applicable. For example, under our license agreement with MGH, we are required to use commercially reasonable efforts to develop and make available to the public licensed products and to satisfy specified diligence milestones within specified timeframes. If we fail to comply with our obligations under this or other of our license agreements, our licensors may have the right to terminate our licenses, in which event we might not be able to market products that are covered by these agreements, or to convert our licenses to non-exclusive licenses, which could materially adversely affect the value of the products we developed under the license agreements. Termination of these 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, or to cease commercialization of licensed technology and products. This could materially adversely affect our business, particularly in the case of our license from MGH.

If we are unable to obtain and maintain patent protection for our technology and products, or if our licensors are unable to obtain and maintain patent protection for the technology or products that we license from them, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be adversely affected.

Our success depends in large part on our and our licensors ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary technology and products. We and our licensors have sought to protect our proprietary position by filing patent applications related to our novel technologies and products that are important to our business. The process of obtaining patent protection is uncertain, and we and our licensors may not succeed in obtaining the patent protection for our novel technologies and products that we seek. If we and our licensors are unable to obtain and maintain patent protection of sufficient scope for our technology and products, our competitors could develop and commercialize technology and products similar or identical to ours, and in that case our ability to successfully commercialize our technology and products may be adversely affected. This risk is greater outside the United States where some aspects of our in-licensed intellectual property are not protected by patents or patent applications.

Moreover, under our license agreement with MGH, we do not have the right to control the preparation, filing and prosecution of the licensed patent applications, to defend the validity and enforceability of the licensed patents against challenges by third parties, or to maintain the licensed patents, covering our technology or products. This could also be the case under any other license agreements we enter into in the future. Therefore, we rely on MGH, and may rely on other licensors in the future, to file, defend and maintain patents that are important to our business. The failure of MGH or other licensors to successfully prosecute, defend and maintain these patents and patent applications in a manner consistent with the best interests of our business could adversely affect our ability to successfully commercialize our technology and products.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors patent rights are highly uncertain. Our and our licensors pending and future patent applications may not result in patents being issued which protect our technology or products or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our

patents or narrow the scope of our patent protection.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore we cannot be certain that we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions.

Assuming the other requirements for patentability are met, currently in the United States, the first to invent the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is generally entitled to the patent. Under the America Invents Act enacted in September 2011, the United States moved to a first inventor to file system in March 2013. We may become involved in patent litigation or reexamination, post-grant review, opposition, derivation or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such litigation or proceeding could reduce

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the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights.

If the scope of the patent protection we or our licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercialize technology and products similar or identical to ours.

Our owned and licensed patents and any owned or licensed patent applications that issue as patents may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to use and commercialize, or to stop or prevent others from using or commercializing, similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. For example, certain of the U.S. patents we exclusively license from MGH will expire in May 2025. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may initiate lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our current and future collaborators to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference proceedings before the U.S. Patent and Trademark Office. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party s intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims that our employees have wrongfully appropriated, used or disclosed intellectual property of their former employers.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees do not appropriate or use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have appropriated, used or disclosed intellectual property, including information forming the basis of patents and patent applications, trade secrets or other proprietary information, of any such employee s former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and our reputation may be harmed.

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Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, such developments could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses, reduce the resources available for development activities and adversely affect our ability to raise additional funds. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial 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.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. The protection available for trade secrets is particularly important with respect to our process for manufacturing AUGMENT and our other potential product candidates, which will involve significant unpatented know-how. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such trade secrets, such as our employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Employee Matters and Managing Growth

Our future success depends on our ability to retain our chief executive officer and other key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on Dr. Dipp, our chief executive officer, Ms. Lawton, our chief operating officer, Mr. Bleck, our chief commercial officer, and Arthur Tzianabos, our chief scientific officer, as well as the other principal members of our management and scientific teams and our scientific co-founders, Drs. Tilly and Sinclair. Although we have entered into employment agreements with Dr. Dipp, Ms. Lawton, Mr. Bleck and Mr. Tzianabos providing for certain benefits, including severance in the event of a termination without cause, these agreements do not prevent them from terminating their employment with us at any time. We do not maintain key person insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

In addition to her role as chief executive officer of our company, Dr. Dipp also serves as a general partner of Longwood Fund, LP, a venture capital investment fund and one of our principal stockholders. It is possible that Dr. Dipp may transition to an executive chairman role at our company at some point in the future, once we have meaningfully advanced our development efforts, grown our company overall and identified and hired a suitable successor. In such event, we will need to recruit and hire a new principal executive officer. Our inability to hire a suitable executive to assume this position in a timely fashion could delay the execution of our business plans or disrupt our operations.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We may not be able to attract and retain these 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, including our scientific co-founders, 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.

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We expect to expand our development, regulatory and future sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of research and development, regulatory affairs and sales and marketing. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

The physical expansion of our operations may also lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Risks Associated with Our Capital Stock

Because we became a reporting company under the Exchange Act by means other than a traditional underwritten initial public offering, we may not be able to attract the attention of research analysts at major brokerage firms.

Because we did not become a reporting company by conducting an underwritten initial public offering, or IPO, of our common stock, security analysts of brokerage firms may not provide coverage of our company. In addition, investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we were to become a public reporting company by means of an IPO because they may be less familiar with our company as a result of more limited coverage by analysts and the media, and because we became public at an early stage in our development. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

The market price of our common stock may be volatile and may fluctuate in a way that is disproportionate to our operating performance.

Even if an active trading market develops for our common stock, our stock price may experience substantial volatility as a result of a number of factors, including:

- sales or potential sales of substantial amounts of our common stock;
- the delay or failure to initiate or complete the AUGMENT Study in humans or adverse results from such study;
- results of preclinical testing or clinical trials of our product candidates including OvaTure or those of our competitors;

- the cost of our development programs;
- the success of competitive products or technologies;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals, new product introductions and commercial results;
- the recruitment or departure of key personnel;
- developments concerning our licensors or manufacturers;
- the results of our efforts to discover, acquire or in-license additional product candidates or products;
- litigation and other developments relating to our issued patents or patent applications or other proprietary rights or those of our competitors;
- disagreement by the FDA or other regulatory agencies regarding the regulatory pathway applicable to AUGMENT;
- regulatory or legal developments in the United States or other countries, particularly with respect to IVF procedures;
- conditions in the pharmaceutical or biotechnology industries;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us; and
- general economic, industry and market conditions.

Many of these factors are beyond our control. The stock markets in general, and the market for pharmaceutical and biotechnological companies in particular, have historically experienced extreme price and volume fluctuations. These fluctuations often have been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors could reduce the market price of our common stock, regardless of our actual operating performance.

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We expect a substantial number of shares will become available for resale in the near future, which may adversely impact any trading market that may develop for our common stock.

As of June 30, 2013, we had outstanding 18,203,156 shares of common stock, including the unvested Founders stock. Of these, 7,630,683 shares may be immediately sold pursuant to the registration statement on Form S-1 we filed on August 29, 2012 (some of which may also be sold pursuant to Rule 144), 3,888,880 shares may be immediately sold pursuant to the registration statement on Form S-1 we originally filed on April 12, 2013 and amended on May 15, 2013 and 37,434 shares may be sold exclusively pursuant to Rule 144.

Of our remaining outstanding shares, 6,574,387 shares are restricted as a result of lock-up agreements. These shares will become free from restriction and eligible for sale as follows:

- 3,064,753 shares pursuant to Rule 144, subject to applicable volume limitations, on October 27, 2013; and
- 3,509,634 shares pursuant to Rule 144, subject to applicable volume limitations and rights of repurchase (which expire over time), on January 25, 2014.

We have also filed a Form S-8 registration statement under the Securities Act to register all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and lock-up agreements.

The availability of a substantial number of shares for resale under registration statements or pursuant to Rule 144 promulgated under the Securities Act may adversely impact any trading market that may develop for our common stock or reduce the price at which such shares may be sold.

We have never paid and do not intend to pay cash dividends.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be our common stockholders sole source of gain for the foreseeable future.

Our executive officers, directors and principal stockholders have the ability to control all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock beneficially own shares, in the aggregate, representing approximately 63.3% of our outstanding capital stock as of June 30, 2013. As a result, if these stockholders were to

choose to act together, they would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act collectively, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Provisions in our certificate of incorporation and by-laws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and by-laws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our common stockholders might otherwise receive a premium price for their shares. These provisions could also 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. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and for nominations to our board of directors;
- limit who may call stockholder meetings;
- prohibit actions by our stockholders by written consent;
- require that stockholder actions be effected at a duly called stockholders meeting;

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- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a poison pill that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or by-laws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a manner prescribed by the statute.

We are an emerging growth company, and may elect to comply with reduced public company reporting requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act enacted in April 2012. For as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various public company reporting requirements. These exemptions include, but are not limited to, (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements, and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years after the first sale of our common equity securities pursuant to an effective registration statement under the Securities Act. However, if certain events occur prior to the end of such five year period, including if we become a large accelerated filer, our annual gross revenues exceed $1 billion or we issue more than $1 billion of non-convertible debt in any three year period, we would cease to be an emerging growth company prior to the end of such five year period. We have taken advantage of certain of the reduced disclosure obligations regarding executive compensation in the filings we have made with the SEC and may elect to take advantage of other reduced burdens in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We cannot predict if investors will find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result of any choice we make to reduce disclosure, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. However, we have irrevocably elected not to avail ourselves of this extended transition period for complying with new or 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 will incur increased costs as a result of operating as a public company, particularly once we cease to be an emerging growth company, and our management will be required to devote substantial time to new compliance initiatives.

As a public reporting company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002 and rules subsequently implemented by the SEC and NASDAQ have imposed various requirements on

public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantial costs to maintain the same or similar coverage.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting, including, once we cease to be an emerging growth company, an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed time period we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor, when required, our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth in the Exhibit Index and such Exhibit Index is incorporated herein by reference.

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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 hereunto duly authorized.

OVASCIENCE, INC.

	By:	/s/ Michelle Dipp	
		Name:	Michelle Dipp, M.D., Ph.D.
Date: August 13, 2013		Title:	*President and Chief Executive Officer (Principal Executive Officer)*
	By:	/s/ Christopher Lindblom	
		Name:	Christopher Lindblom
Date: August 13, 2013		Title:	*Vice President of Finance (Principal Financial and Accounting Officer)*

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Exhibit Index

Exhibit	Description
3.1	Restated Certificate of Incorporation of the Registrant (1)
3.2	Amended and Restated By-laws of the Registrant (1)
10.1	Securities Purchase Agreement, dated as of March 12, 2013, by and among the Company and the persons party thereto (2)
10.2	Registration Rights Agreement, dated March 12, 2013, by and among the Company and the persons party thereto (2)
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Executive Officer.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 by Chief Financial Officer.
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Principal Executive Officer.
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, by Principal Financial Officer.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XTRL Taxonomy Extension Definition
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document

(1) Incorporated by reference to Exhibits 3.1 and 3.2 to the Registrant s Current Report on Form 8-K (File No. 001-35890), filed with the Securities and Exchange Commission on April 30, 2013.

(2) Incorporated by reference to Exhibits 10.1 and 10.2 to the Registrant s Registration Current Report on Form 8-K (File No. 000-54647), filed with the Securities and Exchange Commission on March 14, 2013.

* Submitted electronically herewith. In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q is deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act, is deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise is not subject to liability under these sections.