Atara Biotherapeutics, Inc.
Form 10-Q
November 12, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2014

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

001-36548

(Commission file number)

ATARA BIOTHERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	46-0920988
(State of incorporation)	(I.R.S. Employer Identification No.)
3260 Bayshore Blvd.	
Brisbane, CA	94005
(Address of principal executive offices)	(Zip code)

(415) 287-2410

(Registrant's telephone number, including area code)

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

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

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

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

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

The number of shares of the registrant's Common Stock outstanding as of November 7, 2014 was 20,212,889 shares.

ATARA BIOTHERAPEUTICS, INC.

INDEX

Atara Biotherapeutics, Inc.

Condensed Combined and Consolidated Balance Sheets

(Unaudited)

(In thousands, except share and per share amounts)

	September 30, 2014	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	$ 25,703	$ 51,615
Short-term available-for-sale investments	25,996	—
Prepaid expenses and other current assets	323	193
Total current assets	52,022	51,808
Property and equipment, net	14	8
Other assets	2,084	12
Total assets	$ 54,120	$ 51,828
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 569	$ 606
Accrued compensation	500	331
Income tax payable	63	155
Other accrued liabilities	1,280	432
Total current liabilities	2,412	1,524
Other long-term liabilities	165	230
Total liabilities	2,577	1,754
Commitments and contingencies (Note 5)		
Series A convertible preferred stock—$0.0001 par value, liquidation preference of $20,088	19,909	19,909
Series A-1 convertible preferred stock—$0.0001 par value, liquidation preference of $3,000	2,768	2,768
Series B convertible preferred stock—$0.0001 par value, liquidation preference of $52,000	51,895	38,414
Stockholders' deficit		
Common stock—$0.0001 par value, 12,003,891 and 1,509,712 shares issued and outstanding as of December 31, 2013 and September 30, 2014, respectively	—	1
Additional paid-in capital	7,344	2,200
Notes receivable from stockholder	—	(335)
Accumulated other comprehensive loss	(11)	—
Accumulated deficit	(30,362)	(12,883)

Total stockholders' deficit	(23,029)	(11,017)
Total liabilities, convertible preferred stock and stockholders' deficit	$ 54,120	$ 51,828

See accompanying notes.

Atara Biotherapeutics, Inc.

Condensed Combined and Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(In thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Expenses:				
Research and development	$4,241	$1,134	$9,332	$2,057
Research and development costs paid to Amgen	—	550	1,066	550
General and administrative	1,708	868	7,162	2,591
Total operating expenses	5,949	2,552	17,560	5,198
Loss from operations	(5,949)	(2,552)	(17,560)	(5,198)
Interest income	30	3	59	8
Loss before provision for income taxes	(5,919)	(2,549)	(17,501)	(5,190)
Provision (benefit) for income taxes	—	(13)	(22)	27
Net loss	$(5,919)	$(2,536)	$(17,479)	$(5,217)
Other comprehensive loss, net of tax:				
Unrealized losses on investments	(11)	—	(11)	—
Other comprehensive loss	(11)	—	(11)	—
Comprehensive loss	$(5,930)	$(2,536)	$(17,490)	$(5,217)
Net loss per common share:				
Basic and diluted net loss per common share	$(4.20)	$(2.59)	$(13.07)	$(5.73)
Weighted-average common shares outstanding - basic and diluted	1,410,507	977,778	1,337,501	910,839

See accompanying notes.

Atara Biotherapeutics, Inc.

Condensed Combined and Consolidated Statements of Cash Flows

(Unaudited)

(In thousands)

	Nine months ended September 30,	
	2014	2013
Operating activities		
Net loss	$(17,479)	$(5,217)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash research and development expenses	750	—
Depreciation expense	4	3
Investment premium amortization, net	249	—
Stock-based compensation expense	4,328	1,017
Interest accrued on notes receivable from stockholder	(2)	(3)
Changes in operating assets and liabilities:		
Other assets	(34)	(5)
Prepaid expenses and other current assets	33	(523)
Accounts payable	(37)	512
Income tax payable	(92)	11
Other accrued liabilities	440	542
Accrued compensation	169	186
Net cash used in operating activities	(11,671)	(3,477)
Investing activities		
Purchase of short-term investments	(28,618)	—
Maturities of short-term investments	2,200	—
Purchase of property and equipment	(10)	(3)
Net cash used in investing activities	(26,428)	(3)
Financing activities		
Repayment of notes receivable from stockholder	337	—
Proceeds from sale of convertible preferred stock	13,500	15,087
Offering costs incurred in connection with sale of convertible preferred stock	(19)	(124)
Offering costs incurred in anticipation of initial public filing	(1,631)	—
Net cash provided by financing activities	12,187	14,963
Increase (decrease) in cash and cash equivalents	(25,912)	11,483
Cash and cash equivalents-beginning of period	51,615	4,207
Cash and cash equivalents-end of period	$25,703	$15,690
Non-cash financing activities		
Issuance of common stock for research and development expenses related to technology licensing option	$750	$—
Issuance of Series A-1 convertible preferred stock to Amgen in exchange for license	$—	$1,003
Change in obligation to issue Series A-1 convertible preferred stock to Amgen	$—	$(1,003)

Issuance of common stock upon vesting of stock awards	$65	$80
Change in other long-term liabilities related to non-vested stock awards	$(65)	$251
Restricted stock issued to related party in exchange for notes receivable	$—	$331
Offering costs in anticipation of initial public filing included in other accrued liabilities and accounts payable	$407	$—
Supplemental cash flow disclosure—Cash paid for taxes	$70	$13

See accompanying notes.

Atara Biotherapeutics, Inc.

Notes to Condensed Combined and Consolidated Financial Statements

(Unaudited)

1. Organization and Description of Business

Atara Biotherapeutics, Inc. ("Atara"), Nina Biotherapeutics, Inc. ("Nina"), Santa Maria Biotherapeutics, Inc. ("Santa Maria") and Pinta Biotherapeutics, Inc. ("Pinta") (collectively, the "Company," "we" or "our") were incorporated in August 2012 in Delaware. We are a clinical-stage biopharmaceutical company developing novel therapeutics, with an initial focus on biologics for muscle wasting conditions and oncology. Atara was formed as a management company with the sole purpose of providing management, financial and administrative services for Nina, Pinta and Santa Maria.

Our product candidate portfolio was acquired through licensing arrangements with Amgen Inc. ("Amgen") in exchange for convertible preferred stock, milestone payments and commitments for future royalties. See Note 4 for further information.

Initial Public Offering

In October 2014, we completed our initial public offering of 5,750,000 shares of common stock, including 750,000 shares from the exercise by the underwriters of their overallotment option, at an offering price to the public of $11.00 per share. We received net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions and offering expenses. In connection with the initial public offering, the Company's outstanding shares of convertible preferred stock were automatically converted into 12,298,515 shares of common stock, resulting in the reclassification of $74.6 million from mezzanine equity to additional paid-in capital.

2. Summary of Significant Accounting Policies

Basis of Presentation and Recapitalization

All share and per-share amounts presented in the combined and consolidated financial statements for the nine months ended September 30, 2014 and for the year ended December 31, 2013 and in the notes hereto have been revised to reflect a 1.3-to-1 reverse stock split which became effective July 9, 2014.

The accompanying condensed combined and consolidated financial statements are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and the rules and regulations of the Securities and Exchange Commission (the "SEC"). These financial statements include the financial position, results of operations, and cash flows of the Company, including its wholly-owned subsidiaries. All inter-company accounts and transactions have been eliminated in consolidation.

The accompanying condensed combined and consolidated financial statements should be read in conjunction with the Company's audited combined and consolidated financial statements and notes thereto included in the Company's final prospectus, relating to the Company's initial public offering, filed with the SEC on October 16, 2014.

The interim financial data as of September 30, 2014 and 2013 is unaudited and is not necessarily indicative of the results for a full year or any interim period. In the opinion of the Company's management, the interim data includes all

normal and recurring adjustments necessary for a fair statement of the Company's financial results for the three and nine month periods ending September 30, 2014 and 2013. The December 31, 2013 condensed combined and consolidated balance sheet data has been derived from audited financial statements. Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to SEC rules and regulations relating to interim financial statements.

Prior to March 31, 2014, the accompanying financial statements include the operations of Atara, Nina, Pinta and Santa Maria on a combined basis as the four individual companies were under common ownership and common management since inception. All intercompany transactions have been eliminated. On March 31, 2014, our boards of directors approved and we implemented a recapitalization (the "Recapitalization") in which (a) all the outstanding shares of common stock of Atara were cancelled and forfeited by existing stockholders and (b) the stockholders of Nina, Pinta and Santa Maria exchanged their existing common and convertible preferred stock for newly-issued shares of Atara, with the same rights and privileges as the outstanding capital stock of Nina, Pinta and Santa Maria. The shares were exchanged on a collective nine-for-one basis. The Recapitalization lacked economic substance as the newly-issued shares have the same rights and privileges as the previously outstanding capital stock of Nina, Pinta and Santa Maria and there was no change in ownership percentages of the individual stockholders. As a result of the Recapitalization, Nina, Pinta and Santa Maria became wholly owned subsidiaries of Atara effective March 31, 2014. The Recapitalization is considered a tax-free exchange for US federal income tax purposes.

Because the four individual companies were under common ownership and the Recapitalization lacked economic substance, we accounted for the Recapitalization as a combination of businesses under common control. The assets and liabilities of Nina, Pinta and Santa Maria were recorded by Atara at their historical carrying amounts on March 31, 2014 and beginning March 31, 2014, the financial statements of the Company are presented on a consolidated basis.

Liquidity

We have incurred significant operating losses since inception and have relied on private equity financings to fund our operations. At September 30, 2014, we had an accumulated deficit of $30.4 million. As we continue to incur losses, our transition to profitability will depend on the successful development, approval and commercialization of product candidates and on the achievement of sufficient revenues to support our cost structure. We may never achieve profitability, and unless and until we do, we will need to continue to raise additional capital. Management expects that existing cash and cash equivalents as of September 30, 2014, combined with the proceeds from our initial public offering in October 2014, will be sufficient to fund our current operating plan through the first half of 2017.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates relied upon in preparing these combined and consolidated financial statements include the fair value of common stock, the fair value of preferred stock and estimates related to clinical trial accruals. Actual results could differ materially from those estimates.

Cash and Cash Equivalents

Cash equivalents are defined as short-term, highly liquid investments with original maturities of 90 days or less at the date of purchase, consisting of money market funds that earn interest and dividends overnight.

Investments

Our available-for-sale investments consist primarily of corporate bonds and commercial paper. Investments with original maturities of greater than 90 days are classified as short-term available-for-sale securities on the combined and consolidated balance sheets.

Our investments in available-for-sale securities are reported at fair value. Unrealized gains and losses related to changes in the fair value of securities are recognized in accumulated other comprehensive loss, net of tax, on our combined and consolidated balance sheets. Changes in the fair value of available-for-sale securities impact the statements of operations only when such securities are sold or an other-than-temporary impairment is recognized. Realized gains and losses on the sale of securities are determined by specific identification of each security’s cost basis. We regularly review our investment portfolio to determine if any security is other-than-temporarily impaired, which would require us to record an impairment charge in the period any such determination is made. In making this judgment, we evaluate, among other things, the duration and extent to which the fair value of a security is less than its cost, the financial condition of the issuer and any changes thereto, and our intent to sell, or whether it is more likely than not that we will be required to sell the security before recovery of its amortized cost basis. Our assessment on whether a security is other-than-temporarily impaired could change in the future due to new developments or changes in assumptions related to any particular security.

Fair Value Measurement

The carrying amounts of certain of our financial instruments including cash equivalents, accounts payable and accrued liabilities approximate fair value due to their short maturities. Short-term investments are comprised of available-for-sale securities, which are carried at fair value.

Concentration of Credit Risk and Other Uncertainties

We place cash and cash equivalents in the custody of financial institutions that management believes are of high credit quality, which at times, may be in excess of the amount insured by the Federal Deposit Insurance Corporation. We also have short-term investments in money market funds, corporate bonds and commercial paper backed by US Government or private insurers, which can be subject to certain credit risk. However, we mitigate the risks by investing in high-grade instruments, limiting our exposure to any one issuer, and monitoring the ongoing creditworthiness of the financial institutions and issuers.

We are subject to certain risks and uncertainties and believe that changes in any of the following areas could have a material adverse effect on future financial position or results of operations: ability to obtain future financing; regulatory approval and market acceptance of, and reimbursement for, our product candidates; performance of third-party clinical research organizations and manufacturers upon which we rely; development of sales channels; protection of our intellectual property; litigation or claims against us based on intellectual property, patent, product, regulatory or other factors; and our ability to attract and retain employees necessary to support our growth.

Fair Value of Financial Instruments

Our financial assets and liabilities carried at fair value are primarily comprised of investments in money market funds, corporate bonds and commercial paper. The fair value accounting guidance requires that assets and liabilities be carried at fair value and classified in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities that we have the ability to access

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data such as quoted prices, interest rates and yield curves

Level 3: Inputs that are unobservable data points that are not corroborated by market data

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy. We recognize transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs. There were no transfers between Level 1, Level 2, and Level 3 during 2013 or through September 30, 2014.

The following table represents the fair value hierarchy for our financial assets and financial liabilities measured at fair value on a recurring basis:

	Total Fair Value	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)
	(in thousands)		
At December 31, 2013:			
Cash equivalents:			
Money market funds	$51,615	$51,615	$ —
At September 30, 2014:			
Cash equivalents:			
Money market funds	$25,703	$25,703	$ —

Short-term investments:			
Corporate bonds	$21,799	$—	$ 21,799
Commercial paper	$4,197	$—	$ 4,197

Financial assets and liabilities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. Corporate bonds and commercial paper are valued primarily using market prices of comparable securities, bid/ask quotes, interest rate yields and prepayment spreads and are included in Level 2.

Financial assets and liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies, or similar techniques, and at least one significant model assumption or input is unobservable. We have no Level 3 financial assets and liabilities.

Available-for-sale investments are carried at fair value and are included in the tables above under short-term investments. The aggregate market value, cost basis, and gross unrealized gains and losses of available-for-sale investments by major security type are as follows:

	Total Amortized Cost	Total Unrealized Gain	Total Unrealized Loss	Total Fair Value
	(in thousands)			
At September 30, 2014:				
Short-term investments:				
Corporate bonds	$21,810	$ 3	$ (14)	$21,799
Commercial paper	4,197	—	—	4,197
Total short-term investments	$26,007	$ 3	$ (14)	$25,996

The amortized cost and fair value of available-for-sale debt investments, by contractual maturity, were as follows:

	Total Amortized Cost	Total Fair Value
	(in thousands)	
At September 30, 2014:		
Maturing within one year	$24,917	$24,906
Maturing in one to five years	1,090	1,090
Short-term available for sale investments	$26,007	$25,996

Segment and Geographic Information

We operate and manage our business as one reporting and one operating segment, which is the business of developing and commercializing therapeutics. Our Chief Executive Officer, who is our chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of our assets are located in the United States.

Property and Equipment, Net

Property and equipment are stated at cost and depreciated using the straight-line method over the estimated useful lives of the assets, ranging from three to five years. Maintenance and repairs are charged to operations as incurred.

Long-lived Assets

We evaluate the carrying amount of our long-lived assets whenever events or changes in circumstances indicate that the assets may not be recoverable. An impairment loss would be recognized when estimated future cash flows

expected to result from the use of the asset and its eventual disposition are less than the carrying amount of the asset. To date, there have been no such impairment losses.

Convertible Preferred Stock

We recorded issued convertible preferred stock at fair value on the dates of issuance. The convertible preferred stock is recorded outside of stockholders' deficit because the shares contain liquidation features that are not solely within our control. We have elected not to adjust the carrying values of the convertible preferred stock to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate us to pay the liquidation preferences to holders of shares of convertible preferred stock. Subsequent adjustments to increase the carrying values to the liquidation preferences will be made only when it becomes probable that such a liquidation event will occur.

Estimated Fair Value of Series A-1 Convertible Preferred Stock

In consideration for the licenses of our product candidate portfolio, we issued 5,538,462 shares of Series A-1 convertible preferred stock (615,384 shares after giving effect to the Recapitalization) and paid $250,000 to Amgen.

We estimated the fair value of our Series A-1 preferred stock to be $2,768,000 by using the option pricing model ("OPM"), backsolve method. OPM treats the rights of the holders of shares of preferred and common stock as equivalent to call options on any value of the enterprise above certain break points of value based upon the liquidation preferences of the holders of preferred stock, as well as their rights to participation and conversion. Thus, the estimated value of the Series A-1 convertible preferred stock can be determined by estimating the value of its portion of each of these call option rights. The OPM backsolve method derives the implied equity value of a company from a recent transaction involving the company's own securities issued on an arm's-length basis. This implied equity value was then allocated to each part of our capital structure, including our Series A-1 convertible preferred stock and common stock. Significant assumptions included an estimated volatility of 53.3%, a risk free interest rate of 0.28% and a time to exit of 2.25 years.

Stock-Based Compensation Expense

We account for stock-based compensation expense, including the expense of restricted common stock awards and grants of RSUs and stock options that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant for employee awards and the date when the service performance is completed for non-employees. The fair value for our restricted common stock awards is their intrinsic value, which is the difference between the fair value of the underlying stock at the measurement date and the purchase price. The fair value of our RSUs is the fair value of the underlying stock at the measurement date. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model. Stock-based compensation expense for awards with time-based vesting criteria is recognized as expense on a straight-line basis over the requisite service period. For employees' awards with performance-based vesting criteria, we assess the probability of the achievement of the performance conditions at the end of each reporting period and recognize the share-based compensation costs when it becomes probable that the performance conditions will be met. For non-employees' awards with performance-based vesting criteria, we assess all possible outcomes at the end of each reporting period and recognize the lowest aggregate fair value in the range of possible outcomes. The lowest value in the range of possible outcomes may be zero. For awards that are subject to both service and performance conditions, no expense is recognized until it is probable that performance conditions will be met. Stock-based compensation expense for awards with performance and other vesting criteria is recognized as expense under an accelerated graded vesting model.

Key assumptions used in the Black-Scholes valuation model used for employee stock awards include:

Expected term – The expected term assumption represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method.

Expected volatility – Expected volatility is estimated using comparable public companies' volatility for similar terms.

Expected dividend – We have not historically declared or paid dividends to our stockholders and have no plans to pay dividends; therefore we assumed an expected dividend yield of 0%.

Risk-free interest rate – The risk-free interest rate is based on the yield on U.S. Treasury securities with the expected term of the associated award.

The fair value of non-employee stock options is estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date.

Research and Development Expense

Research and development expense consists of costs incurred in performing research and development activities, including compensation and benefits for research and development employees, an allocation of facility and overhead expenses, expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies, the costs of acquiring and manufacturing clinical trial materials, and other supplies and costs associated with product development efforts, preclinical activities and regulatory operations. Research and development costs are expensed as incurred.

Costs for preclinical study and clinical trial activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services are performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

Income Taxes

We use the assets and liability method to account for income taxes. We record deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the financial statement carrying amounts and the tax basis of assets and liabilities using enacted tax rates expected to be in effect when the differences are expected to reverse. Valuation allowances are provided when necessary to reduce net deferred tax assets to the amount that is more likely than not to be realized. Based on the available evidence, we are unable, at this time, to support the determination that it is more likely than not that our deferred tax assets will be utilized in the future. Accordingly, we recorded a full valuation allowance as of September 30, 2014 and December 31, 2013. We intend to maintain valuation allowances until sufficient evidence exists to support its reversal.

Tax benefits related to uncertain tax positions are recognized when it is more likely than not that a tax position will be sustained during an audit. Interest and penalties related to unrecognized tax benefits are included within the provision for income tax.

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period resulting from transactions from non-owner sources. Other comprehensive loss includes net loss and unrealized losses on available-for-sale investments.

Net Loss per Common Share

Basic and diluted net loss per common share is presented, giving effect to the Recapitalization, including cancellation of existing Atara common stock and a nine-for-one share exchange. Basic net loss per common share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding during the period, without consideration of common stock equivalents. Diluted net loss per common share is computed by dividing the net loss by the weighted-average number of shares of common stock and common share equivalents outstanding for the period. Common share equivalents are only included in the calculation of diluted net loss per common share when their effect is dilutive. Our convertible preferred stock and restricted stock awards are considered to be participating securities as they are entitled to participate in undistributed earnings with shares of common stock. Due to net losses, there is no impact on the net loss per common share calculation in applying the two-class method since the participating securities have no legal requirement to share in any losses.

Potential dilutive securities, which include convertible preferred stock and unvested restricted common stock awards have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per common share and be antidilutive. Therefore, the denominator used to calculate both basic and diluted net loss per common share is the same in all periods presented.

The following shares of potentially dilutive securities give effect to the Recapitalization, and have been excluded from the computations of diluted net loss per common share as the effect of including such securities would be antidilutive:

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Convertible preferred stock	12,299,184	5,766,090	12,249,056	5,186,843
Unvested restricted common stock	631,031	828,118	702,135	796,985

	12,930,215	6,594,208	12,951,191	5,983,828

In addition, 209,959 options have been excluded from the above table as the exercise prices of the underlying options were greater than the average fair value of our common stock for the periods presented.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (the "FASB") issued a new accounting standard to provide guidance on the presentation of management's plans, when conditions or events raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued. The new standard is effective for fiscal years ending after December 15, 2016. The adoption of this standard is not expected to have a material impact on our financial statements.

In June 2014, the FASB amended the definition of a development-stage entity in the Master Glossary of the Accounting Standards Codification. The amendments simplified the financial reporting for development-stage companies by eliminating inception-to-date reporting requirements specific to development stage entities. The revised guidance is effective for annual periods beginning after December 15, 2014; however we early adopted the guidance in the second quarter of 2014. The adoption of this guidance impacted our financial statement presentation, but did not have a material impact on our financial position or results of operations and cash flows.

In May 2014, the FASB issued a new accounting standard, Revenue from Contracts with Customers (Topic 606), which supersedes that revenue recognition requirements in the current standard, Revenue Recognition. The new standard is based on the principle that revenue is recognized to depict the transfer of goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. It also requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. The new standard's effective date for us will be January 1, 2017. We will evaluate the application of this standard when we enter into any contracts with customers.

3. Property and Equipment

Property and equipment consists of computer equipment and software, which is depreciated over the estimated useful lives of the assets, ranging from three to five years. Depreciation and amortization expense was not material for all periods presented.

4. Significant Agreements

Related Party License Agreements - In September 2012, we entered into three license agreements with Amgen for the development, manufacturing, use and distribution of products using certain proprietary compounds. Under the terms of these agreements, we paid $250,000 and issued 5,538,462 shares of Series A-1 convertible preferred stock (615,384 shares after giving effect to the Recapitalization) to Amgen. As described further in Note 5, we may also be required to make additional payments to Amgen based upon the achievement of specified development, regulatory, and commercial milestones, as well as mid-single-digit percentage royalties on future sales of products resulting from development of these purchased technologies, if any. These agreements expire at the end of all royalty obligations to Amgen and, upon expiration, the licenses will be fully paid, royalty-free, irrevocable and non-exclusive. We made a $1.0 million milestone payment to Amgen in the second quarter of 2014.

At December 31, 2013, Amgen owns 9.8% of our outstanding voting capital stock on a combined basis. Amgen does not have any rights to participate in our product candidates' development and is not represented on our boards of directors.

Exclusive Option Agreement – In September 2014, we entered into an exclusive option agreement with Memorial Sloan Kettering Cancer Center ("MSK") under which we have the right to acquire (pursuant to a negotiated form of license agreement) the exclusive worldwide license rights to the three clinical stage T-cell therapies of MSK. The initial option period is for twelve months, with extensions available to extend the term up to 27 months at the option of Atara. Under the terms of the option agreement, we are obligated to use reasonable efforts to prepare a request to be submitted to the US Food and Drug Administration (the "FDA") regarding a meeting to discuss pivotal trials for one of the clinical stage T-cell therapies. In exchange for the exclusive option, we paid MSK $1.25 million in cash and issued 59,761 shares of our common stock to MSK. We estimated the fair value of the common stock issued to MSK to be $750,000. This total of $2.0 million was recorded as research and development expense in our condensed combined and consolidated statement of operations and comprehensive loss in the third quarter of 2014. We will be obligated to pay MSK an additional amount up to $630,000 if we extend the option period.

If we extend the option and enter into the license agreement with MSK, we will be obligated under the license agreement to pay to MSK an upfront cash payment of $4.5 million and additional payments of up to $33.0 million based on a license fee and achievement of specified development, regulatory and sales-related milestones, and to make royalty payments based on sales of the T-cell therapy products.

5. Commitments and Contingencies

Operating Leases

In September 2013, we entered into a noncancelable operating lease for our facility in Westlake Village, California. The lease term commenced in October 2013 and will expire in October 2014. After October 2014, this facility is available to us on a month-to-month lease arrangement. Rent expense for this facility is recognized on a straight-line basis over the term of the lease, and the difference between amounts paid and amounts recorded as rent expense are recorded as deferred rent. Future minimum lease payments under this lease are $31,900 in 2014. We also lease an office facility in Brisbane, California under a sublease that expires in January 2015. Future minimum payments under this lease are $23,220 in 2014 and $811 in 2015.

In September 2014, we entered into a non-cancellable sublease agreement for our corporate headquarters in South San Francisco, California. The sublease term began in November 2014 and ends on January 31, 2017. Total commitments over the term of the sublease are estimated to be approximately $0.4 million.

Rent expense for the three and nine month periods ended September 30, 2014 were $19,867 and $49,620, respectively. Rent expense for the three and nine month periods ended September 30, 2013 were $12,988 and $40,224, respectively.

Related Party License Agreements

Under the terms of our license agreements with Amgen, we are obligated to make additional milestone payments to Amgen of up to $86.0 million upon the achievement of certain development and regulatory approval milestones. Of these milestone payments, $14.0 million relate to milestones for clinical trials. The remaining $72.0 million relate to milestones for regulatory approvals in various territories and are anticipated to be made no earlier than 2017. Thereafter, we are obligated to make tiered payments based on achievement of commercial milestones based upon net sales levels. The maximum payments would be $206.0 million based on sales of over $1 billion for each of three products in a calendar year. We are also obligated to pay mid-single-digit percentage tiered royalties on future net sales of products which are developed and approved as defined by the agreements. Our royalty obligations as to a particular licensed product will be payable, on a country-by-country and product-by-product basis, until the later of (a) the date of expiration of the last to expire valid claim within the licensed patents that covers the manufacture, use or sale, offer to sell, or import of such licensed product by us or a sublicense in such country, (b) loss of regulatory exclusivity or (c) 10 years after the first commercial sale of the applicable licensed product in the applicable country. As of December 31, 2013 and September 30, 2014, there were no outstanding obligations due to Amgen. We made a $1.0 million milestone payment to Amgen in the second quarter of 2014.

In accordance with terms of the agreements, we use commercially reasonable efforts to pay costs related to the preparation, filing, prosecution, defense and maintenance of the patents covered by the license agreements. During the three and nine month periods ended September 30, 2014, we incurred expenses of $447,518 and $842,228, respectively, related to the preparation, filing and maintenance of patents. During the three and nine month periods ended September 30, 2013, the corresponding amounts were $206,434 and $688,909, respectively.

Indemnification Agreements

In the normal course of business, we enter into contracts and agreements that contain a variety of representations and warranties and provide for indemnification for certain liabilities. The exposure under these agreements is unknown because it involves claims that may be made against us in the future but have not yet been made. To date, we have not paid any claims or been required to defend any action related to our indemnification obligations. However, we may record charges in the future as a result of these indemnification obligations. We also have indemnification obligations to our directors and executive officers for specified events or occurrences, subject to some limits, while they are serving at our request in such capacities. There have been no claims to date and we believe the fair value of these indemnification agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of September 30, 2014 and December 31, 2013.

6. Convertible Preferred Stock and Stockholders' Deficit

Convertible preferred shares issued and authorized as of September 30, 2014 and December 31, 2013 were as follows:

	As of September 30, 2014		
	Authorized Shares	Outstanding Shares	Carrying Value (dollars in thousands)
Series A convertible preferred stock	5,150,699	5,150,699	$ 19,909
Series A-1 convertible preferred stock	615,384	615,384	2,768

Series B convertible preferred stock	6,532,432	6,532,432	51,895
	12,298,515	12,298,515	$ 74,572

	As of December 31, 2013							
	Nina		Pinta		Santa Maria		Combined Total	
	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value
	(dollars in thousands)							
Issued and outstanding:								
Series A convertible preferred stock	15,452,114	$ 2,306	15,452,114	$9,963	15,452,114	$7,640	46,356,342	$19,909
Series A-1 convertible preferred stock	1,846,154	573	1,846,154	1,355	1,846,154	840	5,538,462	2,768
Series B convertible preferred stock	14,509,579	2,496	14,509,579	17,960	14,509,579	17,958	43,528,737	38,414
	31,807,847	$ 5,375	31,807,847	$29,278	31,807,847	$26,438	95,423,541	$61,091
Authorized:								
Series A convertible preferred stock	15,452,114		15,452,114		15,452,114		46,356,342	
Series A-1 convertible preferred stock	1,846,154		1,846,154		1,846,154		5,538,462	
Series B convertible preferred stock	16,960,012		16,960,012		16,960,012		50,880,036	
	34,258,280		34,258,280		34,258,280		102,774,840	

Original issuance prices of Series A convertible preferred stock, prior to issuance costs, were $0.152, $0.650 and $0.498 per share, for Nina, Pinta and Santa Maria, respectively, or $1.30 per share on a combined basis. Original issuance prices of Series B convertible preferred stock, prior to issuance costs were $0.173, $1.240 and $1.240 per share, for Nina, Pinta and Santa Maria, respectively, or $2.653 per share on a combined basis. Amgen contributed licenses for issued Series A-1 convertible preferred stock with fair values of $0.310, $0.734 and $0.455 per share for Nina, Pinta and Santa Maria, respectively, or $1.500 per share on a combined basis.

In connection with the Recapitalization on March 31, 2014, the stockholders of Nina, Pinta and Santa Maria exchanged three shares of each company’s preferred stock for one share of Atara preferred stock (a collective nine-for-one basis). The deemed original issuance prices of the new Atara preferred shares, for the calculation of the dividends and liquidation preference discussed below are $3.900, $4.875, and $7.960 for Series A, Series A-1, and

Series B, respectively.

Nina, Pinta and Santa Maria issued convertible preferred stock with the same rights and privileges to the same investors. As of December 31, 2013, Atara had not issued any convertible preferred stock. In connection with the Recapitalization on March 31, 2014, Atara issued convertible preferred stock with the same rights and privileges and with the same ownership percentages as the convertible preferred stock previously issued by Nina, Pinta and Santa Maria.

In October 2014, in connection with the completion of our initial public offering, all outstanding shares of Series A convertible preferred stock, Series A-1 convertible preferred stock and Series B convertible preferred stock were converted into 12,298,515 shares of common stock and $74.6 million of mezzanine equity was reclassified to additional paid-in capital.

The significant rights, privileges, and preferences of our convertible preferred stock are as follows:

Dividend Provisions

The holders of the outstanding shares of convertible preferred stock are entitled to receive, when and if declared by our boards of directors, noncumulative annual dividends at a rate of 8% of the $20,087,750 and $52,000,000 liquidation preferences for the Series A and Series B convertible preferred stock, respectively, and 8% of the $3,000,000 liquidation preference for Series A-1 convertible preferred stock. After payments of such dividends, any additional dividends are paid to common and convertible preferred stock holders on an as-converted to common stock basis. No dividends were declared or paid through September 30, 2014.

Liquidation Preference

In the event of any liquidation, dissolution, winding up or change in control of the Company, the holders of Series B convertible preferred stock are entitled to receive a liquidation amount of $52,000,000 plus all declared but unpaid dividends prior and in preference to the holders of Series A and Series A-1 convertible preferred stock and the common stock. Following payment of these liquidation amounts, if proceeds for distribution remain, the holders of the Series A-1 convertible preferred and Series A convertible preferred stock, pro rata as a single group, are entitled to receive a liquidation amount of $20,087,750 and $3,000,000, respectively, plus all declared but unpaid dividends prior and in preference to the common stockholders. Thereafter, any proceeds remaining for distribution would be distributed pro rata among the common stockholders. Holders of convertible preferred stock may choose to receive the liquidation preference described above as preferred stockholders or instead may participate with the common stock in remaining liquidation proceeds on an as-converted to common stock basis.

Conversion Rights

Each share of convertible preferred stock is convertible, at the option of the holder and at any time, into shares of common stock on a one-for-one basis, subject to certain anti-dilution adjustments.

Each share of convertible preferred stock, subject to certain anti-dilution adjustments, will be automatically converted into one fully paid and nonassessable share of common stock at the applicable conversion rate upon the earlier of: (i) an initial public offering with a pre-initial public offering valuation that results in a price to the public of at least three times the Series B issue price (reduced to 1.6 times following the Recapitalization—see Note 2) and minimum proceeds to us of $30,000,000 or (ii) the date specified by a vote of the holders of a majority of outstanding shares of preferred stock.

Subject to customary exceptions, our amended and restated certificates of incorporation provide anti-dilution protection for holders of convertible preferred stock in the event that we issue additional shares of common stock, options or rights to purchase common stock or securities convertible into common stock without consideration or at a price per share that is less than the then-effective conversion price of any series of the convertible preferred stock, which is referred to as a dilutive issuance. Our amended and restated certificates of incorporation provide that the conversion price shall be adjusted to protect holders of convertible preferred stock from certain dilutive issuances based on a weighted-average formula.

In addition to the anti-dilution protections described above, the conversion price of the convertible preferred stock is subject to adjustments for stock splits, dividends and recapitalizations.

Voting Rights

The holder of each share of convertible preferred stock has the right to one vote for each share of common stock into which such share of convertible preferred stock could be converted. Additionally, specific protective provisions require approval of the holders of a majority of the outstanding shares of convertible preferred stock.

Election of Directors

The members of the boards of directors of Nina, Pinta and Santa Maria were identical for all three companies for the periods presented and were elected as follows: (i) one person was elected by the holders of the common stock; (ii) two persons were elected by the holders of our Series A convertible preferred stock; (iii) one person was elected by the holders of our Series B convertible preferred stock; and (iv) the remaining directors were elected by the holders of our common stock and convertible preferred stock as a single class.

The members of the board of directors of Atara after the Recapitalization were elected as follows: (i) one person was elected by the holders of the common stock; (ii) two persons were elected by the holders of our Series A convertible preferred stock; (iii) one person was elected by the holders of our Series B convertible preferred stock; and (iv) the remaining directors were elected by the holders of our common stock and convertible preferred stock as a single class.

7. Common Stock and Additional Paid-in Capital

Common stock authorized, issued and outstanding and additional paid-in capital as of September 30, 2014 and December 31, 2013 were as follows:

	Authorized	Outstanding
As of December 31, 2013	162,461,535	12,003,891
Issuance of common stock upon vesting of awards	—	644,710
Recapitalization:		
Cancellation of Atara shares	(923,076)	(923,076)
Tender of Nina, Pinta and Santa Maria shares	(161,538,459)	(11,725,525)
Issuance of Atara shares	17,948,717	1,302,835
Issuance of common stock upon vesting of awards - post Recapitalization	—	147,116
Issuance of common stock for research and development expenses related to technology licensing option	—	59,761
As of September 30, 2014	17,948,717	1,509,712

	As of December 31, 2013									
	Nina		Pinta		Santa Maria		Atara		Combined Total	
	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value	Shares	Carrying Value
	(dollars in thousands)									
Issued and outstanding:										
Common stock, par value	3,693,605	$—	3,693,605	$—	3,693,605	$1	923,076	$—	12,003,891	$1
Additional paid-in capital	—	147	—	1,017	—	1,036	—	—	—	2,200
	3,693,605	$147	3,693,605	$1,017	3,693,605	$1,037	923,076	$—	12,003,891	$2,201
Authorized	53,846,153		53,846,153		53,846,153		923,076		162,461,535	

We have reserved the following shares of common stock for issuance:

	September 30, 2014
Conversion of Series A convertible preferred stock	5,150,699
Conversion of Series A-1 convertible preferred stock	615,384

Conversion of Series B convertible preferred stock	6,532,432
Common stock available for grant of stock awards	1,136,543
Common stock issuable for options and RSUs outstanding and non-vested restricted stock	1,698,120
	15,133,178

Restricted Common Stock

In August 2012, in connection with our formation, our CEO purchased 9,595,384 shares of restricted common stock at a nominal per share purchase price. The shares were issued subject to certain vesting conditions, restrictions on transfer and a Company right of repurchase of any unvested share at their original purchase price. These shares are placed in escrow until vested, and have rights to vote and participate in dividends and distributions. 7,996,153 of these shares have service and fundraising vesting conditions. Under the service vesting condition, shares vest monthly over 48 months, commencing from the first closing of Series A convertible preferred stock financing on October 22, 2012. 1,599,231 of these shares are subject to performance milestones and fundraising vesting conditions. The fundraising vesting conditions for all shares were satisfied as of December 31, 2013. All shares subject to service vesting conditions are subject to accelerated vesting in the event of certain change of control transactions.

The combined grant date intrinsic value for this award was $1,704,094.

As of September 30, 2014, there was $1,611,029 of unrecognized stock-based compensation expense related to this restricted common stock. Upon the closing of our initial public offering in October 2014, $508,962 of this stock-based compensation will be recognized in our combined and consolidated statement of operations and comprehensive loss for the three months ended December 31, 2014 and the remainder will be recognized over the remaining service periods through 2016.

In March 2013, an Atara employee purchased 2,423,074 shares of restricted common stock for $331,170. The shares were issued under our 2012 Equity Incentive Plan (as discussed below) and are subject to certain vesting conditions, restrictions on transfer and a Company right of repurchase of any unvested shares at their original purchase price. These shares are placed in escrow until vested, and have rights to vote and participate in dividends and distributions. Under these agreements, the shares vest as follows: 2,319,228 shares vest over four years, with one-quarter vesting after one year of service and the remainder vesting in equal installments over the subsequent thirty-six months, and 103,846 shares vest upon achievement of certain performance milestones. Vesting of all shares is subject to acceleration of vesting in the event of certain change of control transactions.

As of September 30, 2014, there was $302,206 of unrecognized stock-based compensation expense related to this restricted common stock. Upon the closing of our initial public offering in October 2014, $28,319 of this stock-based compensation expense will be recognized in our combined and consolidated statement of operations and comprehensive loss for the three months ended December 31, 2014 and the remainder will be recognized over the remaining service periods through 2016.

The restricted common stock was purchased with secured promissory notes totaling $331,170. The notes bear interest at an annual interest rate of 1.5% and are due on the earlier of five years following the purchase date, the sale or transfer of the related shares, termination of employment or the date prior to the date of a filing of a registration statement with the Securities and Exchange Commission. The notes are secured by shares of common stock owned by the employee and are included in stockholders' deficit in our combined and consolidated balance sheets. In March and June 2014, the outstanding balances were repaid.

The amounts paid for both restricted stock purchases were initially recorded as other long-term liabilities. As shares vest, we reclassify liabilities to equity and report shares as outstanding in the combined and consolidated statements of convertible preferred stock and stockholders' deficit. At December 31, 2013, 4,157,739 shares had vested and are classified as equity. Restricted stock shares not vested at December 31, 2013 totaled 7,860,719 shares and are expected to vest over three years.

Prior to the Recapitalization, 4,802,450 shares had vested and were classified as equity. On March 31, 2014, these shares were exchanged for 533,605 shares of Atara common stock. Restricted shares not vested at March 31, 2014 totaled 7,216,006 shares and these shares were exchanged for 801,778 shares of Atara restricted common stock. As of September 30, 2014, restricted shares not vested totaled 654,663 shares.

As both the Chief Executive Officer and the Atara employee were consultants of Nina, Pinta and Santa Maria through the Recapitalization date, we accounted for these awards as non-employee stock-based awards. Following the Recapitalization, these awards were accounted as employee awards based upon the fair market value of common stock on March 31, 2014. Total stock-based compensation expense related to these awards was as follows:

	Three months	Nine months

	ended September 30,		ended September 30,	
	2014	2013	2014	2013
Research and development	$86	$90	$918	$203
General and administrative	346	249	3,356	814
	$432	$339	$4,274	$1,017

As this stock-based compensation expense relates to shares of common stock for which the fundraising condition was met and our right of repurchase has lapsed, these amounts have been recorded as additional paid-in capital in our combined and consolidated balance sheets.

2012 Equity Incentive Plans

We adopted the Nina 2012 Equity Incentive Plan, Pinta 2012 Equity Incentive Plan and Santa Maria 2012 Equity Incentive Plan (collectively, the "2012 plans") in November 2012. Under the terms of the 2012 plans, we may grant options, restricted stock awards and RSUs to employees, directors, consultants and other service providers. Employees typically receive an award upon commencement of employment and non-employee members of our boards of directors receive an award in connection with their appointment. At December 31, 2013, the aggregate number of awards available to be issued under the 2012 plans was 17,021,923 shares of common stock. RSUs expire at the earlier of seven years from the date of grant or two years following the service termination date (or, for RSUs granted after January 2014, the service termination date). Generally, if any shares subject to an award expire, or are forfeited, terminated or cancelled without the issuance of shares, the shares are added back into the total shares available for issuance under the 2012 plans.

Through December 31, 2013, we have granted restricted common stock and RSUs under the 2012 plans. The RSUs have a time-based service condition and a liquidity-based performance condition, and will vest when both conditions are met. We have determined that the liquidity-based performance condition is not probable of occurring and have recorded no compensation expense related to the RSUs during the period from August 22, 2012 (inception) to December 31, 2013. As of December 31, 2013, there was approximately $788,335 of unrecognized stock-based compensation expense related to nonvested RSUs.

As the restricted stock awards and the RSUs were granted by Nina, Pinta and Santa Maria, the grants are considered to be non-employee awards until the Recapitalization and the fair value of the awards was remeasured at each period end by multiplying the number of unvested shares by the per-share fair value of common stock at each period end. Following the Recapitalization, the awards granted to employees were accounted for based on the fair value of common stock on March 31, 2014. A summary of the restricted stock awards and RSUs granted and vested on a combined and consolidated basis during the period from December 31, 2012 to September 30, 2014 is as follows:

	Combined Number of Units/Awards	Weighted-Average Grant Date Fair Value
Unvested at December 31, 2013	4,261,774	$ 0.133
Granted—Restricted stock units	5,375,742	$ 0.606
Vested—Restricted stock awards	(144,951)	$ 0.045
Unvested at March 30, 2014	9,492,565	$ 0.402
Recapitalization (Note 2)	(8,437,856)	
Unvested at March 31, 2014	1,054,709	$ 3.619
Granted—Restricted stock units*	13,692	$ 12.545
Vested—Restricted stock awards	(36,058)	$ 0.404
Forfeitures	(66,153)	$ 8.593
Unvested at September 30, 2014	966,190	$ 3.561

* Granted under the 2014 Equity Incentive Plan discussed below

Through September 30, 2014, we have granted restricted common stock and RSUs under the 2012 plans and the 2014 Equity Incentive Plan ("2014 EIP") discussed below. Our RSUs granted have a time-based service condition and a liquidity-based performance condition, and will vest when both conditions are met. We have determined that the

liquidity-based performance condition is not probable of occurring and have recorded no compensation expense related to the RSUs. As of September 30, 2014, there was $7,353,086 of unrecognized stock-based compensation expense related to nonvested RSUs. Upon the closing of our initial public offering in October 2014, $3,978,563 of this stock-based compensation expense will be recognized in our combined and consolidated statement of operations and comprehensive loss for the quarter ended December 31, 2014 and $3,374,523 will be recognized over the remaining service periods through 2018.

2014 Equity Incentive Plan

We adopted the 2014 EIP on March 31, 2014 as part of the Recapitalization. In connection with the Recapitalization, Atara assumed the plans of Nina, Pinta and Santa Maria and all outstanding RSUs and restricted stock awards granted under such plans. At the time of settlement, each employee or consultant will receive one share of common stock of Atara for three shares in each of Nina, Pinta and Santa Maria (collectively, a nine-for-one exchange). At the date of Recapitalization, RSUs and restricted stock awards issued by Nina, Pinta and Santa Maria to Atara employees become employee awards and the awards' grant dates were established as the Recapitalization date. Under the terms of the 2014 EIP, the aggregate number of awards available for issuance is 2,449,230 shares of common stock as of September 30, 2014. This aggregate amount includes the remaining shares that were previously available for issuance under the existing 2012 plans (1,294,041 shares of common stock, after giving effect to the nine-for-one exchange).

In May 2014, our board of directors amended and restated our 2014 EIP, which was approved by our stockholders in June 2014. Our 2014 EIP, as amended and restated, became effective on October 15, 2014 upon the pricing of our initial public offering. The maximum number of shares of our common stock that may be issued pursuant to stock awards under the 2014 EIP increased by 1,076,923 shares to a total of 3,526,153 shares. Additionally, the number of shares of our common stock reserved for issuance pursuant to stock awards under our 2014 EIP will automatically increase on January 1 of each year for a period of up to ten years, beginning on January 1, 2015 and ending on and including January 1, 2024, by 5% of the number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares of our common stock that may be issued upon the exercise of Incentive Stock Options under the 2014 EIP increased to 11,538,461.

Stock options

Options under the 2014 EIP are granted for periods of up to 10 years and at prices no less than 100% of the estimated fair value of the shares on the date of grant as determined by the board of directors, provided, however, that the exercise price of an ISO and NSO granted to a 10% shareholder cannot be less than 110% of the estimated fair value of the shares on the date of grant. Options granted to employees and non-employees generally vest ratably over four years and expire in seven years. Generally, if any shares subject to an award expire, or are forfeited, terminated or cancelled without the issuance of shares, the shares are added back into the total shares available for issuance under the plans. There were no options granted prior to the third quarter of 2014. The following is a summary of stock option activity for the nine months ended September 30, 2014:

	Number of Awards	Exercise Price Per Share	Remaining Contractual Term
Outstanding at December 31, 2013	—	$ —	—
Granted	209,959	12.55	
Exercised	—	—	—
Forfeited or expired	—	—	—
Outstanding at September 30, 2014	209,959	$ 12.55	6.88
Vested and expected to vest at September 30, 2014	209,959	$ 12.55	6.88
Exercisable at September 30, 2014	—	$ —	—

The estimated fair value of options granted to employees and non-employees during the nine months ended September 30, 2014 was $1.2 million and $288,000, respectively. The fair value of each option issued was estimated at the date of grant using the Black-Scholes valuation model with the following weighted-average assumptions:

	Nine Months Ended September 30, 2014	
	Employees	Non-Employees
Risk-free interest rate	1.74%	2.24%
Expected life of options in years	4.6	7.0
Expected volatility of underlying stock	65.7%	65.8%
Expected dividend yield	0.0%	0.0%

During the three and nine months ended September 30, 2014, we recognized $54,305 of stock-based compensation expense related to stock options granted. $48,710 of this stock-based compensation expense was recorded in research and development expense and the remainder was recorded in general and administrative expense. As of September 30, 2014, there was $1.4 million of unrecognized stock-based compensation cost related to stock options that are expected to vest. This expense is expected to be recognized over the weighted-average remaining vesting period of 3.85 years.

Employee Stock Purchase Plan

Our board of directors adopted the 2014 Employee Stock Purchase Plan (the "2014 ESPP") in May 2014, and our stockholders approved the 2014 ESPP in June 2014. The 2014 ESPP became effective on October 15, 2014 upon the pricing of our initial public offering. The 2014 ESPP is administered by our board of directors and the Compensation Committee of our board of directors. The maximum number of shares of our common stock that may be issued under the 2014 ESPP is 230,769 shares. Additionally, the number of shares of our common stock reserved for issuance under our ESPP will automatically increase each year for a period of up to ten years, beginning on January 1, 2015 and continuing through and ending on January 1, 2024, by the lessor of (i) 1% of the total number of shares of our capital stock outstanding on the December 31 of the preceding calendar year, (ii) 230,769 shares of our common stock, or (iii) a lower number as determined by our board of directors.

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

Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations together with the section of this quarterly report titled "Selected Combined and Consolidated Financial Data" and our combined and consolidated financial statements and related notes included elsewhere in this quarterly report. This discussion and other parts of this quarterly report contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this quarterly report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel therapeutics for serious unmet medical needs, with an initial focus on muscle wasting conditions and oncology. Our product candidates are biologics targeting myostatin and activin, members of the TGF-ß protein superfamily, which play roles in the growth and maintenance of muscle and many other body tissues. Our lead product candidate, PINTA 745, is in a Phase 2 clinical trial for PEW in ESRD patients. Our second product candidate is STM 434, and we commenced a Phase 1 clinical study of STM 434 for ovarian cancer and other solid tumors in the second half of 2014. We have five additional molecules in preclinical development. We intend to license or acquire additional product candidates to develop and commercialize.

Our current product candidate portfolio was acquired through licensing arrangements with Amgen in exchange for convertible preferred stock and future milestone payments and royalties. Through these arrangements, we obtained licenses to patent rights and the ability to use certain proprietary know-how to develop and commercialize a portfolio of seven product candidates. The arrangement did not provide for the acquisition of employees, facilities or ongoing services. We are responsible for obtaining all regulatory approvals and developing commercial scale manufacturing processes to enable eventual commercialization of these product candidates. Under the terms of these agreements, we made an upfront payment of $250,000 and issued 615,384 shares of Series A-1 convertible preferred stock on a combined basis to Amgen. We are also required to make additional payments of up to $86.0 million to Amgen based upon the achievement of certain development and regulatory approval milestones, as well as additional payments based on achievement of commercial milestones and future net sales of products resulting from development of these product candidates, if any. Of the $86.0 million, $14.0 million in potential payments relate to milestones for clinical trials.

We are considered a development-stage company under GAAP, and have only a limited operating history. Since our inception in 2012, we have devoted substantially all of our resources to identify, acquire and develop our product candidates, including conducting preclinical and clinical studies and providing general and administrative support for these operations. Through September 30, 2014, we have funded our operations to date primarily from the issuance and sale of convertible preferred stock.

In October 2014, we completed our initial public offering of 5,750,000 shares of common stock at an offering price to the public of $11.00 per share. We received net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions and offering expenses. In connection with our initial public offering, the Company's shares of convertible preferred stock were automatically converted into 12,298,515 shares of common stock, resulting in the reclassification of $74.6 million from mezzanine equity to additional paid-in capital in the fourth quarter of 2014.

We have never generated revenues and have incurred net losses since inception. Our net losses were $17.5 million and $8.8 million for the nine months ended September 30, 2014 and the year ended December 31, 2013, respectively. As of September 30, 2014, we had an accumulated deficit of $30.4 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development programs and from general and administrative expenses associated with our operations. Our cash and short-term available-for-sale investment balances at September 30, 2014 totaled $51.7 million, which we intend to use to fund our operations in the near term.

Financial Overview

Basis of Presentation and Recapitalization

Atara, Nina, Pinta and Santa Maria were incorporated in August 2012. Atara was formed as a management company with the sole purpose of providing management, financial and administrative services for Nina, Pinta and Santa Maria. Since inception, Atara, Nina, Pinta and Santa Maria have been under common management and common ownership for all periods and as of all dates prior to our recapitalization on March 31, 2014, we have presented the results of operations and financial condition of the four companies on a combined basis. The combined financial statements include the accounts of the four individual companies since inception, with intercompany transactions eliminated.

On March 31, 2014, we implemented a recapitalization in which (a) all the outstanding shares of common stock of Atara were cancelled and forfeited by existing stockholders and (b) the stockholders of Nina, Pinta and Santa Maria exchanged their existing common and convertible preferred stock for newly-issued shares of Atara, in the same proportions and with the same rights and privileges as the outstanding capital stock of Nina, Pinta and Santa Maria, on a collective nine-for-one basis. Atara assumed the separate equity incentive plans sponsored by Nina, Pinta and Santa Maria and all outstanding RSUs and restricted stock awards granted under such plans. At the time of RSU settlement, each employee or consultant will receive one share of common stock of Atara for three RSUs in each of Nina, Pinta, and Santa Maria (collectively, a nine-for-one exchange). We refer to this transaction as our recapitalization. As a result of the recapitalization, Nina, Pinta and Santa Maria became wholly owned subsidiaries of Atara effective March 31, 2014. The recapitalization was accounted for as a combination of businesses under common control and the assets and liabilities of Nina, Pinta and Santa Maria were recorded by Atara at their historical carrying amounts on March 31, 2014. Beginning March 31, 2014, our financial statements are presented on a consolidated basis, with all intercompany transactions eliminated. Except as otherwise noted, all share and per share amounts presented in this “Management’s Discussion and Analysis of Financial Condition and Results of Operations” give effect to the recapitalization.

Revenues

To date, we have not generated any revenues. We do not expect to receive any revenues from any product candidates that we develop until we obtain regulatory approval and commercialize our products or enter into collaborative agreements with third parties.

Research and Development Expenses

The largest component of our total operating expenses since inception has been our investment in research and development activities, including the preclinical and clinical development of our product candidates. Research and development expenses consist of costs incurred in performing research and development activities, including compensation and benefits for research and development employees, including stock-based compensation, an allocation of facility and overhead expenses, expenses incurred under agreements with contract research organizations and investigative sites that conduct clinical trials and preclinical studies, the costs of acquiring and manufacturing clinical trial materials and other supplies and costs associated with product development efforts, preclinical activities and regulatory operations. Research and development costs are expensed as incurred.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of our product candidates. Our current planned research and development activities include the following:

- increased enrollment and completion of our Phase 2 clinical trial of PINTA 745;
- commencement of our Phase 1 clinical study of STM 434;

process development and manufacturing of drug supply for ATA 842 to support IND-enabling studies; and
evaluation of our exclusive option to license certain T-cell therapies from MSK.

In addition to our product candidates that are in clinical development, we believe it is important to continue our substantial investment in a diverse pipeline of new product candidates to continue to build the value of our product candidate pipeline and our business. We plan to continue to advance our most promising early product candidates into preclinical development with the objective to advance these early-stage programs to human clinical studies over the next several years.

Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs, and timing of clinical trials and development of our product candidates will depend on a variety of factors, including:

the scope, rate of progress, and expenses of our ongoing as well as any additional clinical trials and other research and development activities;
future clinical trial results;

uncertainties in clinical trial enrollment rates or drop-out or discontinuation rates of patients;
potential additional safety monitoring or other studies requested by regulatory agencies;
significant and changing government regulation; and
the timing and receipt of any regulatory approvals.

The process of conducting the necessary clinical research to obtain FDA approval is costly and time consuming and the successful development of our product candidates is highly uncertain. The risks and uncertainties associated with our research and development projects are discussed more fully in the section of this quarterly report titled “Risk Factors.” As a result of these risks and uncertainties, we are unable to determine with any degree of certainty the duration and completion costs of our research and development projects, or if, when, or to what extent we will generate revenues from the commercialization and sale of any of our product candidates that obtain regulatory approval. We may never succeed in achieving regulatory approval for any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, allocated facilities costs, and other expenses for outside professional services, including legal, human resources, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation. We anticipate that our general and administrative expenses will continue to increase in the future as we increase our headcount to support our continued research and development and potential commercialization of our product candidates. We also anticipate increased expenses related to audit, legal, regulatory, and tax-related services associated with maintaining compliance with NASDAQ listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with being a public company.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and marketable securities as well as interest on notes receivables issued to one of our employees related to the purchase of restricted common stock.

Critical Accounting Policies and Significant Judgments and Estimates

This discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate and accrue expenses, the largest of which is related to accrued research and development expenses. This process involves reviewing contracts and purchase orders, identifying services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual costs.

Costs for preclinical study and clinical trial activities are recognized based on an evaluation of our vendors’ progress towards completion of specific tasks, using data such as patient enrollment, clinical site activations or information

provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. Our estimates of accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. For the three and nine months ended September 30, 2014 and 2013, there have been no material changes to our estimates of accrued research and development expenses. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

Stock-based Compensation

Because our common stock was not publicly traded through September 30, 2014, our board of directors, with the assistance of management, used significant judgment to estimate the fair value of our common stock. Since the closing of our initial public offering in October 2014, the fair value of our common stock has been determined based on the closing price of our common stock on The NASDAQ Global Select Market.

We account for stock-based compensation expense, including the expense of restricted common stock awards and grants of RSUs and stock options that may be settled in shares of our common stock, based on the fair values of the equity instruments issued. The fair value is determined on the measurement date, which is generally the date of grant for employee awards and the date when the service performance is completed for non-employees. The fair value for our restricted common stock awards is their intrinsic value, which is the difference between the fair value of the underlying stock at the measurement date and the purchase price. The fair value of our RSUs is the fair value of the underlying stock at the measurement date. The fair value for our stock option awards is determined at the grant date using the Black-Scholes valuation model. Stock-based compensation expense for awards with time-based vesting criteria is recognized as expense on a straight-line basis over the requisite service period. For employees' awards with performance-based vesting criteria, we assess the probability of the achievement of the performance conditions at the end of each reporting period and recognize the share-based compensation costs when it becomes probable that the performance conditions will be met. For non-employees' awards with performance-based vesting criteria, we assess all possible outcomes at the end of each reporting period and recognize the lowest aggregate fair value in the range of possible outcomes. The lowest value in the range of possible outcomes may be zero. For awards that are subject to both service and performance conditions, no expense is recognized until it is probable that performance conditions will be met. Stock-based compensation for awards with performance and other vesting criteria is recognized as expense under the accelerated graded vesting model.

Key assumptions used in the Black-Scholes valuation model used for employee stock awards include:

Expected term – The expected term assumption represents the period that our stock-based awards are expected to be outstanding and is determined using the simplified method.

Expected volatility – Expected volatility is estimated using comparable public companies' volatility for similar terms.

Expected dividend – We have not historically declared or paid dividends to our stockholders and has no plans to pay dividends; therefore we assumed an expected dividend yield of 0%.

Risk-free interest rate – The risk-free interest rate is based on the yield on U.S. Treasury securities with the expected term of the associated award.

The fair value of non-employee stock options is estimated using the Black-Scholes valuation model with assumptions generally consistent with those used for employee stock options, with the exception of the expected term, which is the remaining contractual life at each measurement date.

Income Taxes

We recognize deferred income taxes for temporary differences between the basis of assets and liabilities for financial statement and income tax purposes. We periodically evaluate the positive and negative evidence bearing upon realizability of our deferred tax assets. Based upon the weight of available evidence, which includes our historical operating performance, reported cumulative net losses since inception and difficulty in accurately forecasting our future results, we maintained a full valuation allowance on the net deferred tax assets for all periods presented. We

intend to maintain a full valuation allowance on the US deferred tax assets for the foreseeable future until sufficient positive evidence exists to support reversal of the valuation allowance.

At December 31, 2013, we had federal and state net operating loss carryforwards of approximately $7.2 million, respectively, which, if not utilized, begin to expire in various amounts beginning in the year 2032.

Under Section 382 of the Code, our ability to utilize net operating loss carryforwards or other tax attributes, such as research tax credits, in any taxable year may be limited if we have experienced an “ownership change.” Generally, a Section 382 “ownership change” occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws. During 2014, we completed a Section 382 study of transactions in our stock through December 31, 2013.

The study concluded that we have experienced at least one ownership change since inception and that our utilization of net operating loss carryforwards will be subject to annual limitations. These results are reflected in the above carryforward amounts. Our ability to utilize our net operating loss carryforwards may be further limited as a result of subsequent ownership changes including potential changes in connection with or after our proposed initial public offering. Further, other provisions of the Code may limit our ability to utilize federal net operating losses incurred before the recapitalization to offset income or gain realized after the recapitalization unless such income or gain is realized by the same entity that originally incurred such losses. All such limitations could result in the expiration of carryforwards before they are utilized.

We had no unrecognized tax benefits as of September 30, 2014 and December 31, 2013. Our policy is to recognize interest and penalties related to income taxes as a component of income tax expense. No interest and penalties related to income taxes have been recognized in the statements of operations and comprehensive loss in 2014 and 2013.

Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with GAAP. Internal control over financial reporting includes: maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management's authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our financial statements would be prevented or detected. Furthermore, our controls and procedures can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls or procedures, and misstatements due to error or fraud may occur and not be detected on a timely basis.

Our management has determined that we had a material weakness in our internal control over financial reporting as of September 30, 2014 and December 31, 2013 relating to the design and operation of our closing and financial reporting processes. We have concluded that this material weakness in our internal control over financial reporting is due to the fact that we do not yet have the appropriate resources with the appropriate level of experience and technical expertise to oversee our closing and financial reporting processes.

In order to remediate this material weakness, we are taking the following actions:

- we have hired a full-time controller and transitioned our Chief Financial Officer from a consulting role to a full-time chief financial officer role;
- we have hired and are continuing to actively seek additional accounting and finance staff members to augment our current staff and to improve the effectiveness of our closing and financial reporting processes; and
- we are formalizing our accounting policies and internal controls documentation and strengthening supervisory reviews by our management.

In connection with the initiatives we are implementing to remediate the material weakness, we expect to incur additional compensation expense as we hire additional financial accounting staff and improve our accounting and financial reporting systems. The initiatives we are implementing are subject to continued management review supported by confirmation and testing, as well as audit committee oversight. We expect to complete the measures above as soon as practicable and will continue to implement measures to remedy our internal control deficiencies in order to meet the deadline imposed by Section 404 of the Sarbanes-Oxley Act of 2002. However, we cannot be certain

that the measures we have taken or might take in the future will ensure that we will maintain adequate controls over our financial processes and reporting in the future.

Notwithstanding the material weakness that existed as of September 30, 2014 and December 31, 2013, our management has concluded that the combined and consolidated financial statements included elsewhere in this quarterly report present fairly, in all material respects, our financial position, results of operation and cash flows in conformity with GAAP.

If we fail to fully remediate this material weakness or fail to maintain effective internal controls in the future, it could result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis, which could cause investors to lose confidence in our financial information or cause our stock price to decline. Our independent registered public accounting firm has not assessed the effectiveness of our internal control over financial reporting and, under the JOBS Act, will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as an "emerging growth company," which may increase the risk that weaknesses or deficiencies in our internal control over financial reporting go undetected.

Emerging Growth Company Status

We are an "emerging growth company" as defined in the JOBS Act, and therefore we may take advantage of certain exemptions from various public company reporting requirements. As an "emerging growth company:"

- we will present no more than two years of audited financial statements and no more than two years of related management's discussion and analysis of financial condition and results of operations;
- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our auditors on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act;
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not require stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

However, we are choosing to irrevocably opt out of the extended transition periods available under the JOBS Act for complying with new or revised accounting standards. We will remain an "emerging growth company" for up to five years, although we will cease to be an "emerging growth company" upon the earliest of: (1) the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering, (2) the last day of the first fiscal year in which our annual gross revenues are $1 billion or more, (3) the date on which we have, during the previous rolling three-year period, issued more than $1 billion in non-convertible debt securities, and (4) the date on which we are deemed to be a "large accelerated filer" as defined in the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Results of Operations

Comparison of the Three Months Ended September 30, 2014 and 2013

Research and development expenses

	Three months ended September 30,		Increase (Decrease)
	2014	2013	
	(in thousands)		
Research and development	$4,241	$1,134	$ 3,107
Research and development costs paid to Amgen	—	550	(550)
Total research and development expense	$4,241	$1,684	$ 2,557

Research and development expenses increased during the three months ended September 30, 2014 compared to the same period in 2013 and consisted of the following costs by program:

	Three months ended September 30,	
	2014	2013
	(in thousands)	
PINTA 745	$660	$795
STM 434	512	517
ATA 842	144	7
Option to license T-cell therapies	2,000	—
Employee and overhead cost	925	365
Total	$4,241	$1,684

PINTA 745 costs decreased slightly in the three months ended September 30, 2014 compared to the quarter ended September 30, 2013 due primarily to a $0.6 million purchase of clinical supplies from Amgen to support the Phase 2 clinical trial that commenced during the fourth quarter of 2013. This decrease was offset by clinical trial costs incurred in 2014.

STM 434 program costs for the three months ended September 30, 2014 were comparable to the prior year. Manufacturing costs for clinical supplies decreased by $0.3 million, but were offset by increased start-up costs related to the Phase I clinical study of STM 434 that commenced in the second half of 2014.

The option to license T-cell therapies cost for the three months ended September 30, 2014 included upfront expense of $2.0 million for our exclusive option agreement with MSK for the worldwide license rights to three clinical stage T-cell therapies. In exchange for the exclusive option, we paid MSK $1.25 million in cash and issued 59,761 shares of our common stock to MSK. The estimated fair value of the common stock issued to MSK was $750,000.

Employee and overhead costs increased by $0.6 million in 2014 as compared to the 2013 quarter as a result of increased recruiting and payroll-related costs.

General and administrative expenses

	Three months ended September 30,		Increase
	2014	2013	(Decrease)
	(in thousands)		
General and administrative	$1,708	$868	$ 840

General and administrative expenses increased in the three months ended September 30, 2014 compared to the quarter ended September 30, 2013 due to a $0.1 million increase in stock-based compensation costs, $0.4 million of increased legal and accounting fees associated with the audit of our financial statements and corporate costs in advance of our initial public offering and $0.2 million of additional payroll-related costs. Personnel costs and stock-based compensation costs were higher in the three months ended September 30, 2014 compared to the same period in 2013 due to increased headcount.

Comparison of the Nine Months Ended September 30, 2014 and 2013

Research and development expenses

	Nine months ended September 30,		Increase
	2014	2013	(Decrease)
	(in thousands)		
Research and development	$9,332	$2,057	$ 7,275
Research and development costs paid to Amgen	1,066	550	516
Total research and development	$10,398	$2,607	$ 7,791

Research and development expenses increased during the nine months ended September 30, 2014 compared to the same period in 2013 and consisted of the following costs by program:

	Nine months ended September 30,	
	2014	2013
	(in thousands)	
PINTA 745	$1,795	$1,003
STM 434	3,662	742
ATA 842	224	12
Option to license T-cell therapies	2,000	—
Employee and overhead cost	2,717	850
Total	$10,398	$2,607

PINTA 745 costs increased by $0.8 million in the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 due primarily to a $1.4 million increase in outside consultants' and third party costs to support the Phase 2 clinical trial that commenced during the fourth quarter of 2013. This increase was partially offset by a $0.6 million decrease in costs incurred in 2013 to acquire clinical supply.

STM 434 program costs increased by $2.9 million in the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 due to a $1.0 million milestone payment to Amgen, $0.9 million in increased outside manufacturing costs for clinical drug supply and approximately $1.0 million of increased third party costs related to the upcoming Phase 1 clinical study of STM 434, which commenced in the second half of 2014.

The option to license T-cell therapies cost for the three months ended September 30, 2014 included upfront expense of $2.0 million for our exclusive option agreement with MSK for the worldwide license rights to three clinical stage T-cell therapies. In exchange for the exclusive option, we paid MSK $1.25 million in cash and issued 59,761 shares of our common stock to MSK. The estimated fair value of the common stock issued to MSK was $750,000.

Employee and overhead costs increased by $1.9 million in 2014 as compared to 2013 primarily as a result of increased payroll-related costs resulting from increased headcount and recruiting expenses.

General and administrative expenses

	Nine months ended September 30,		
	2014	2013	Increase (Decrease)
	(in thousands)		
General and administrative	$7,162	$2,591	$ 4,571

General and administrative expenses increased in the nine months ended September 30, 2014 compared to the nine months ended September 30, 2013 due to a $2.5 million increase in stock-based compensation costs, $1.2 million of increased legal and accounting fees associated with the audit of our financial statements and corporate costs in advance of our initial public offering and $0.7 million of additional payroll-related costs. Personnel costs and stock-based compensation costs were higher in the nine months ended September 30, 2014 compared to the same period in 2013 due to increased headcount.

Liquidity and Capital Resources

We have incurred cumulative losses and negative cash flows from operations since our inception in 2012, and we had an accumulated deficit of $12.9 million as of December 31, 2013 and $30.4 million as of September 30, 2014. It will be several years, if ever, before we have a product candidate ready for commercialization, and we anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may raise through a combination of equity offerings, debt financings, other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

In October 2014, we completed our initial public offering and received net proceeds of approximately $55.8 million, after deducting underwriting discounts and commissions and offering expenses. In January 2014, we completed the sale and issuance of additional shares of Series B convertible preferred stock with gross proceeds of $13.5

million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our cash and cash equivalents and short-term investments are held in bank and custodial accounts and consist of money market mutual funds, corporate bonds and commercial paper. Management expects that existing cash and cash equivalents as of September 30, 2014, combined with the proceeds from our initial public offering in October 2014, will be sufficient to fund our current operating plan through the first half of 2017.

Working capital was $49.6 million and $50.3 million as of September 30, 2014 and December 31, 2013, respectively. Included in working capital were cash, cash equivalents, and short-term investments of $51.7 million and $51.6 million as of September 30, 2014 and December 31, 2013, respectively.

Our cash, cash equivalents and short-term investments balances were as follows:

Our cash,	September 30, 2014	December 31, 2013
	(in thousands)	
Cash and cash equivalents	$ 25,703	$ 51,615
Short-term available-for-sale investments	25,996	—
Total cash and cash equivalents and short-term available-for-sale investments	$ 51,699	$ 51,615

Cash Flows

Comparison of the Nine Months Ended September 30, 2014 and 2013

The following table details the primary sources and uses of cash for each of the periods set forth below:

	Nine months ended September 30,	
	2014	2013
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$(11,671)	$(3,477)
Investing activities	(26,428)	(3)
Financing activities	12,187	14,963
Net increase (decrease) in cash and cash equivalents	$(25,912)	$11,483

Operating activities

For the nine months ended September 30, 2014 and 2013, we used $11.7 million and $3.5 million of net cash in operating activities, respectively. The $8.2 million increase in cash used in operating activities was primarily due to the increase in net loss from the quarterly periods in 2013 to 2014 of $12.3 million, offset in part by the $3.3 million increase in stock-based compensation for the 2014 period and by the $0.8 million non-cash charge for research and development expenses related to our exclusive option to license certain T-cell therapies from MSK.

Investing activities

Net cash used in investing activities during the nine months ended September 30, 2014 consisted primarily of $28.6 million invested in short-term available-for-sale securities, offset by maturities of $2.2 million.

Financing activities

Net cash provided by financing activities for the nine months ended September 30, 2013 was $15.0 million, consisting of proceeds from the sale of shares of Series A convertible preferred stock net of offering costs. Net cash provided by financing activities for the nine months ended September 30, 2014 was $12.2 million, consisting primarily of $13.5 million proceeds from the sale of shares of Series B convertible preferred stock, offset in part by cash used for

offering costs incurred in connection with our October 2014 initial public offering.

Operating Capital Requirements and Plan of Operations

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize one of our current or future product candidates. We anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of and seek regulatory approvals for our product candidates, and begin to commercialize any approved products. We are subject to all of the risks inherent in the development of new products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We have incurred and expect to continue to incur additional costs associated with operating as a public company and we anticipate that we will need substantial additional funding in connection with our continuing operations.

We expect that our existing cash and cash equivalents, including the proceeds from our October 2014 initial public offering, will be sufficient to enable us to complete planned preclinical and clinical trials for our lead product candidates through at least the first half of 2017. In order to complete the process of obtaining regulatory approval for our lead product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our lead product candidates, if approved, we will require substantial additional funding.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

the timing and costs of our planned clinical trials for our product candidates;
the timing and costs of our planned preclinical studies of our product candidates;
our success in establishing and scaling commercial manufacturing capabilities;
the number and characteristics of product candidates that we pursue;
the outcome, timing and costs of seeking regulatory approvals;
subject to receipt of regulatory approval, revenues received from commercial sales of our product candidates;
the terms and timing of any future collaborations, licensing, consulting or other arrangements that we may establish;
the amount and timing of any payments we may be required to make in connection with the licensing, filing, prosecution, maintenance, defense and enforcement of any patents or patent applications or other intellectual property rights; and
the extent to which we in-license or acquire other products and technologies.

Contractual Obligations and Commitments and Off-Balance Sheet Arrangements

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments” in our final prospectus dated October 15, 2014 filed pursuant to Rule 424(b) of the Exchange Act with the SEC on October 16, 2014.

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 in the rules and regulations of the SEC.

Item 3. Quantitative and Qualitative Disclosure about Market Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2013, and September 30, 2014 we had cash and cash equivalents and short-term available-for-sale investments of $51.6 million, and $51.7 million, respectively. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of US interest rates, particularly because our investments are in short-term securities. Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% increase in interest rates would not have a material effect on the fair market value of our portfolio.

30

Item 4.Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our Chief Executive Officer and Chief Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) of the Exchange Act as of September 30, 2014. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2014 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosure.

Our disclosure controls and procedures were not effective as of September 30, 2014 because of the material weakness in internal control over financial reporting described in Item 1A of the Quarterly Report on Form 10-Q in "Risk Factors – Risks Related to Ownership of our Common Stock – We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected." In that section, we explain that, as a private company, we previously did not maintain an effective control environment, which is the foundation for effective internal control over financial reporting, as evidenced by: (i) an insufficient number of personnel to perform control monitoring activities, (ii) an insufficient number of personnel with an appropriate level of GAAP knowledge, and (iii) inadequate processes for the preparation and review of our consolidated financial statements.

Changes in Internal Control Over Financial Reporting

In order to remediate this material weakness, we have hired a full-time controller and transitioned our Chief Financial Officer from a consulting role to a full-time chief financial officer role. We have hired and are continuing to actively seek additional accounting and finance staff members to augment our current staff and we are formalizing our accounting policies and internal controls documentation and strengthening supervisory reviews by our management. While we have implemented a plan to remediate this weakness, our remediation efforts are still ongoing and we cannot assure you that we will be able to remediate this material weakness.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently party to any material litigation or other material legal proceedings.

Item 1A. Risk Factors

Risk factors

You should carefully consider all of the risk factors and uncertainties described below, in addition to other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our combined and consolidated financial statements and related notes, before investing in our common stock. If any of the following risks materialize, our business, financial condition and results of operations could be seriously harmed. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report on Form 10-Q.

Risks Related to Our Financial Results and Capital Needs

We have incurred substantial losses since our inception and anticipate that we will continue to incur substantial and increasing losses for the foreseeable future.

We are a clinical-stage biopharmaceutical company. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to prove effective, gain regulatory approval or become commercially viable. We do not have any products approved by regulatory authorities and have not generated any revenues from product sales to date, and have incurred significant research, development and other expenses related to our ongoing operations and expect to continue to incur such expenses. As a result, we have not been profitable and have incurred significant operating losses in every reporting period since our inception. For the nine months ended September 30, 2014 and the year ended December 31, 2013, we reported a net loss of $17.5 million and $8.8 million, respectively, and we had an accumulated deficit of $30.4 million as of September 30, 2014.

We do not expect to generate revenues for many years, if at all. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate these losses to increase as we continue to research, develop and seek regulatory approvals for our product candidates and any additional product candidates we may acquire, and potentially begin to commercialize product candidates that may achieve regulatory approval. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. If any of our product candidates fail in clinical trials or do not gain regulatory approval, or if approved, fail to achieve market acceptance, we may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. We anticipate that our expenses will increase in the future as we continue to invest in research and development of our existing product candidates, investigate and potentially acquire new product candidates and expand our manufacturing and commercialization activities.

We have a limited operating history, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our company was formed in August 2012. Our operations to date have been limited to organizing and staffing our company, acquiring product and technology rights and conducting product development activities for our product candidates. We have not yet demonstrated our ability to successfully complete any Phase 2 or Phase 3 clinical trials, obtain regulatory approval, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization for any of our product candidates. Consequently, any predictions about our future success, performance or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We currently have no source of revenues. We may never generate revenues or achieve profitability.

To date, we have not generated any revenues from product sales or otherwise. Our ability to generate revenues from product sales and achieve profitability will depend on our ability to commercialize products, including any of our current product candidates, and other product candidates that we may develop, in-license or acquire in the future. Even if we are able to successfully achieve regulatory approval for these product candidates, we do not know when we will generate revenues, if at all. Our ability to generate revenues also depends on a number of additional factors, including our ability to:

successfully complete development activities, including the necessary clinical trials;
complete and submit biologics license applications ("BLAs") to the FDA and obtain US regulatory approval for indications for which there is a commercial market;
complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities in Europe, Asia and other jurisdictions;
obtain coverage and adequate reimbursement from third parties, including government and private payors;
set a commercially viable price for our products;

establish and maintain supply and manufacturing relationships with reliable third parties and ensure adequate, legally compliant manufacturing of bulk drug substances and drug products to maintain that supply;
obtain commercial quantities of our products at acceptable cost levels;
achieve market acceptance of our products, if any;
attract, hire and retain qualified personnel;
protect our rights in our intellectual property portfolio;
develop a commercial organization capable of sales, marketing and distribution for any products we intend to sell ourselves in the markets in which we choose to commercialize on our own; and
find suitable distribution partners to help us market, sell and distribute our approved products in other markets.

In addition, because of the numerous risks and uncertainties associated with product development, including that our product candidates may not advance through development or achieve the endpoints of applicable clinical trials, we are unable to predict the timing or amount of increased expenses, or when or if we will be able to achieve or maintain profitability. Even if we are able to complete the development and regulatory process for any product candidates, we anticipate incurring significant costs to commercialize these products.

Even if we are able to generate revenues from the sale of our products, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and may be forced to reduce our operations.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

We expect to expend substantial resources for the foreseeable future continuing clinical development and manufacturing of PINTA 745, preclinical and clinical development and manufacturing of STM 434 and advancing and expanding our preclinical research pipeline, including ATA 842. These expenditures will include costs associated with research and development, potentially acquiring new product candidates, evaluating and potentially exercising our option to license certain T-cell therapies from MSK, conducting preclinical studies and clinical trials, potentially obtaining regulatory approvals and manufacturing products, as well as marketing and selling products approved for sale, if any. Under the terms of our license agreements with Amgen, we are obligated to make additional milestone payments to Amgen of up to $86.0 million upon the achievement of certain development and regulatory approval milestones. In addition, other unanticipated costs may arise. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates.

Our future capital requirements depend on many factors, including:

the scope, progress, results and costs of researching and developing our other product candidates, and conducting preclinical studies and clinical trials;
the timing of, and the costs involved in, obtaining regulatory approvals for our other product candidates if clinical trials are successful;
the cost of commercialization activities for our product candidates, if any of these product candidates is approved for sale, including marketing, sales and distribution costs;
the cost of manufacturing our product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
the costs to in-license future product candidates or technologies, including the exercise of our option to license certain T-cell therapies from MSK;

the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
the timing, receipt and amount of sales of, or royalties on, our future products, if any; and
the emergence of competing technologies or other adverse market developments.

Based on our current operating plan, we believe that the net proceeds we received from our initial public offering in October 2014, together with our existing cash and cash equivalents and short-term investments, will be sufficient to fund our projected operating requirements through the first half of 2017. However, our operating plan may change as a result of many factors currently unknown to us, and we may need additional funds sooner than planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. We do not have any committed external source of funds. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more of our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates.

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

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, or grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future and we may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. At December 31, 2013, we had federal and state net operating loss carryforwards of approximately $7.2 million, respectively, which, if not utilized, begin to expire in various amounts beginning in the year 2032. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, if over a rolling three-year period, the cumulative change in our ownership exceeds 50% (as determined under applicable Treasury regulations), our ability to utilize our US federal net operating loss, or NOL, carryforwards and other pre-change tax attributes (such as research tax credits) to offset future taxable income or taxes may be limited. We have experienced at least one ownership change since inception and our utilization of NOL carryforwards will therefore be subject to annual limitation. Our ability to utilize our NOL carryforwards may be further limited as a result of subsequent ownership changes, including potential changes in connection with our proposed initial public offering. Similar rules may apply under state tax laws. Further, other provisions of the Code may limit our ability to utilize NOLs incurred before the recapitalization to offset income or gain realized after the recapitalization, unless such income or gain is realized by the same entity that originally incurred such NOLs. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited. We have not yet determined the amount of the cumulative change in our ownership resulting from our initial public offering or any resulting tax loss limitations. Such limitations could result in the expiration of our carryforwards before they can be utilized and, if we are profitable, our future cash flows could be adversely affected due to our increased tax liability.

34

Risks Related to the Development of Our Product Candidates

We are very early in our development efforts and have only two product candidates in clinical development. All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business will be materially harmed.

We are very early in our development efforts and have only two product candidates, PINTA 745 and STM 434, in clinical development. All of our other product candidates are currently in preclinical development. We have invested substantially all of our efforts and financial resources in identifying and developing potential product candidates and conducting preclinical studies, clinical trials and manufacturing activities. Our ability to generate revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. The success of our product candidates will depend on several factors, including the following:

completion of preclinical studies and clinical trials with positive results;
receipt of regulatory approvals from applicable authorities;
obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
manufacturing products at an acceptable cost;
launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
acceptance of the product candidates, if and when approved, by patients, the medical community and third-party payors;
effectively competing with other therapies;
obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates;
protecting our rights in our intellectual property portfolio;
maintaining a continued acceptable safety profile of the products following approval; and
maintaining and growing an organization of scientists and business people who can develop and commercialize our products and technology.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which would materially harm our business.

Our future success is dependent on the regulatory approval of our two lead product candidates.

We do not have any products that have gained regulatory approval. Currently, our only clinical-stage product candidates are PINTA 745, which is in a Phase 2 clinical trial, and STM 434, for which we commenced a Phase 1 study in the second half of 2014. Our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our product candidates in a timely manner. We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical and clinical studies, generally including two well-controlled Phase 3 trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a BLA or other submission or to obtain regulatory approval;
- failure to obtain approval of the manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

Even if a product candidate were to successfully obtain approval from the FDA and comparable foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for one of our product candidates in one or more jurisdictions, or any approval contains significant limitations, we may not be able to obtain sufficient funding to continue the development of that product or generate revenues attributable to that product candidate. Also, any regulatory approval of our current or future product candidates, once obtained, may be withdrawn.

The results of preclinical testing or earlier clinical studies are not necessarily predictive of future results, and PINTA 745 and STM 434, and any other product candidate we advance into clinical studies or trials, may not have favorable results in later clinical studies or trials or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of an investigational drug. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Despite the results reported in earlier preclinical studies or clinical trials for our product candidates, we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market PINTA 745 or STM 434 or any of our other product candidates in any particular jurisdiction. If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive, can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Product candidates in later stages of clinical trials may fail to show

the desired safety and efficacy traits despite having progressed through preclinical studies and early clinical trials.

We may experience delays in our ongoing or future clinical studies or trials and we do not know whether planned clinical studies or trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. There can be no assurance that the FDA will not put clinical studies or trials of any of our product candidates on clinical hold in the future. Clinical studies or trials may be delayed, suspended or prematurely terminated for a variety of reasons, such as:

delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;

delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical study;

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

delay or failure in obtaining institutional review board ("IRB") approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;

withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;

delay or failure in recruiting and enrolling suitable subjects to participate in a trial;

delay or failure in subjects completing a trial or returning for post-treatment follow-up;

clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;

inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication;

failure of our third-party clinical trial managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;

delay or failure in adding new clinical trial sites;

ambiguous or negative interim results or data or results that are inconsistent with earlier results or data;

feedback from the FDA, the IRB, data safety monitoring boards, or a comparable foreign regulatory authority, or results from earlier stage or concurrent preclinical and clinical studies, that might require modification to the protocol for the trial;

a decision by the FDA, the IRB, a comparable foreign regulatory authority, or us, or a recommendation by a data safety monitoring board or comparable foreign regulatory authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;

unacceptable risk-benefit profile, unforeseen safety issues or adverse side effects;

failure to demonstrate a benefit from using a drug;

difficulties in manufacturing or obtaining from third parties sufficient quantities of a product candidate for use in clinical studies or trials;

lack of adequate funding to continue the clinical study or trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional clinical studies or increased expenses associated with the services of our CROs and other third parties; or

changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical study or trial.

Patient enrollment, a significant factor in the timing of clinical studies or trials, is affected by many factors including the size and nature of the patient population, the severity of the disease under investigation, the proximity of subjects to clinical sites, the patient referral practices of physicians, the eligibility criteria for the trial, the design of the clinical trial, ability to obtain and maintain patient consents, risk that enrolled subjects will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. We may not be able to continue clinical studies for STM 434 and clinical trials for PINTA 745 or initiate clinical studies for any future product candidates if we are unable to locate and enroll a sufficient number of eligible participants in these studies or trials as required by the FDA or other regulatory authorities. Even if we are able to enroll a sufficient number of patients in our clinical studies or trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of our studies may be delayed or our studies could become too expensive to complete. We rely on CROs, other vendors and clinical study or trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

If we experience delays in the completion or termination of any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any delays in completing our clinical trials for our current product candidates may also decrease the period of exclusivity in our corresponding product candidate license from Amgen. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our product candidates, their delivery methods or dosage levels could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authority. As a result of safety or toxicity issues that we may experience in our clinical studies or trials in the future, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our studies or trials could reveal an unacceptably high severity and prevalence of side effects. In such an event, our studies or trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may have a material adverse effect on our business, results of operations, financial condition, cash flows and future prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including that:

- we may be forced to suspend marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label that could diminish the usage or otherwise limit the commercial success of such products;
- we may be required to conduct post-market studies;
- we may be required to change the way the product is administered;
- we could be sued and held liable for harm caused to subjects or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved.

We may not be able to obtain orphan drug exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. If our Phase 1 clinical study of STM 434 is successful, we intend to apply for orphan drug status for STM 434 for ovarian cancer.

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

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

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

In addition to regulations in the United States, to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We have had no significant interactions with foreign regulatory authorities to date. The approval procedure 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 includes all of the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. We may not be able to obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA 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. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished, our business prospects could decline and this could materially adversely affect our business, results of operations and financial condition.

Even if our product candidates receive regulatory approval, they may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, quality control, further development, labeling, packaging, storage, distribution, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-market information. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance by our contract manufacturing organizations (“CMOs”) and CROs for any post-approval clinical trials that we conduct. For example, if labeling is ultimately approved for PINTA 745, it will likely include restrictions on use due to the specific patient population and manner of use in which the product candidate was evaluated and the safety and efficacy data obtained in those evaluations. In addition, PINTA 745 may be required to include a boxed warning, or “black box,” regarding PINTA 745 being teratogenic, or causing of fetal or embryotic malformations, in animal studies. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a risk evaluation and mitigation strategy, impose significant restrictions on a product’s indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices (“cGMP”), current Good Clinical Practices (“GCP”) and other regulations. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the

manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical studies;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or

seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the Department of Justice ("DOJ"), the Office of Inspector General of the Department of Health and Human Services ("HHS"), state attorneys general, members of Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities. For example, in the event PINTA 745 obtains regulatory approval, we believe these authorities will closely monitor the use of this product candidate to determine whether it is being used impermissibly as a muscle-builder by athletes and others. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA. Any actual or alleged failure to comply with labeling and promotion requirements may have a negative impact on our business.

In the United States, engaging in impermissible promotion of our products for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines and agreements that would materially restrict the manner in which we promote or distribute our drug products. These false claims statutes include the federal False Claims Act, which allows any individual to bring a lawsuit against a pharmaceutical company on behalf of the federal government alleging submission of false or fraudulent claims, or causing to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government prevails in the lawsuit, the individual will share in any fines or settlement funds. Since 2004, these False Claims Act lawsuits against pharmaceutical companies have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements based on certain sales practices promoting off-label drug uses. This growth in litigation has increased the risk that a pharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, agree to comply with burdensome reporting and compliance obligations, and be excluded from the Medicare, Medicaid and other federal and state healthcare programs. If we do not lawfully promote our approved products, we may become subject to such litigation and, if we are not successful in defending against such actions, those actions could compromise our ability to become profitable.

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

Concurrent with the license of our existing product candidates, we acquired manufacturing process know-how and certain intermediates, as well as certain supplies intended for clinical use, from Amgen. We are in the process of outsourcing the manufacture of additional drug substance and drug product for our preclinical and clinical studies using the know-how and supplies we received from Amgen. Our CMOs will need to conduct significant development work to prepare each of our product candidates for studies, trials and commercial readiness.

Additionally, the process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including but not limited to:

the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. Product defects can also occur unexpectedly. For example, we recently encountered a small number of cracked vials in certain STM 434 drug product lots. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate

and remedy the contamination; and

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

Any adverse developments affecting manufacturing operations for our product candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls or other interruptions in the supply of our drug substance and drug product. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our products could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community, including major operators of dialysis and cancer clinics which could adversely affect our ability to operate our business and our results of operations.

We may not successfully identify, acquire, develop or commercialize new potential product candidates.

Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in-license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the success of our business will depend on our ability to expand our product pipeline through in-licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in-license or acquire them.

We may form strategic alliances in the future, and we may not realize the benefits of such alliances.

We may form strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our existing business. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy. If we license products or acquire businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenues or specific net income that justifies such transaction. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or if we lose any of our CROs, we may not be able to obtain regulatory approval for or commercialize our product candidates on a timely basis, if at all.

We have relied upon and plan to continue to rely upon third-party CROs and contractors to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for the execution of our preclinical and clinical trials, and we control only some aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to assist in conducting our preclinical studies in accordance with Good Laboratory Practices, or GLP, and the Animal Welfare Act requirements. We and our CROs are required to comply with federal regulations and GCP, which are international standards meant to protect the rights and health of patients that are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our regulatory applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP requirements. We are also required to register ongoing clinical trials

and post the results of completed clinical trials on a government-sponsored database, clinicaltrials.gov, within a specified timeframe. Failure to comply with these regulations may require us to repeat preclinical and clinical trials, which would delay the regulatory approval process and result in adverse publicity.

Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources, including experienced staff, to our ongoing clinical, nonclinical and preclinical programs. They may also have relationships with other entities, some of which may be our competitors. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. For example, there was an error in the randomization of patients and inventory distribution to our clinical sites for our Phase 2 clinical trial for PINTA 745, resulting in the unblinding of the initial six patients and a restart of the trial. CRO or contractor errors could cause our results of operations and the commercial prospects for our product candidates to be harmed, our costs to increase and our ability to generate revenues to be delayed.

Our internal capacity for clinical trial execution and management is limited and therefore we have relied on third parties. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. For example, on July 22, 2014 we became aware of a draft report for a preclinical study conducted with STM 217, a compound similar to STM 434 that we also licensed from Amgen. Results from this study led to the amendment of our planned clinical trial for STM 434. Although we believe we now have all data previously generated by Amgen for our licensed product candidates, other data from studies previously conducted by Amgen may emerge in the future. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. If any of our relationships with our third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms.

We have no experience manufacturing our product candidates on a clinical or commercial scale and have no manufacturing facility. We are dependent on third parties for the manufacturing of our product candidates and our supply chain, and if we experience problems with any of these third parties, the manufacturing of our product candidates could be delayed.

We do not own or operate facilities for the manufacturing of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently rely on single source CMOs for the production of our product candidates and on single source suppliers of some of the materials incorporated in our product candidates. To meet our projected needs for clinical supplies to support our activities through regulatory approval and commercial manufacturing, the CMOs with whom we currently work will need to increase the scale of production and, for PINTA 745 and STM 434, we will need to demonstrate comparability of the material produced by these CMOs to the material that was previously produced by Amgen. We may need to identify additional CMOs for continued production of supply for our product candidates. We have not yet identified alternate suppliers in the event the current CMOs that we utilize are unable to scale production, or if we otherwise experience any problems with them. Manufacturing biologic drugs is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers, transfer manufacturing procedures to these alternative suppliers, and demonstrate comparability of material produced by such new suppliers. New manufacturers of any product would be required to qualify under applicable regulatory requirements. These manufacturers may not be able to manufacture our compounds at costs, or in quantities, or in a timely manner necessary to complete development of our product candidates or make commercially successful products. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. In addition, should the FDA not agree with our physical quality

specifications and comparability assessments for these materials, further clinical development of our product candidate would be substantially delayed and we would incur substantial additional expenses.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to synthesize and manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

Any significant disruption in our supplier relationships could harm our business. Any significant delay in the supply of a product candidate or its key materials for an ongoing clinical study could considerably delay completion of our clinical studies, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these key materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our product candidates.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.

We rely upon a combination of patents, trade secrets and confidentiality agreements to protect the intellectual property related to our technology and product candidates. For our two most advanced product candidates, PINTA 745 and STM 434, we own or license a number of issued patents and pending patent applications covering the product candidates' compositions of matter and methods of use. For PINTA 745, the expected expiration dates range from 2026 to 2034 for US patents and patent applications, if issued, and from 2023 to 2034 for patents and patent applications, if issued, in jurisdictions outside the United States, exclusive of possible patent term extensions. For STM 434, the expected expiration dates range from 2027 through 2035 for US patents and patent applications, if issued, and from 2026 through 2035 for patents and patent applications, if issued, in jurisdictions outside the United States, exclusive of possible patent term extensions. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is generally uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the US Patent and Trademark Office, or USPTO, and non-US patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding

patentable subject matter or the scope of claims allowable in biotechnology patents.

Consequently, the patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries for many reasons. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. We may be unaware of prior art that could be used to invalidate an issued patent or prevent our pending patent applications from issuing as patents. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim.

Even if patents have issued or do successfully issue from patent applications, and even if such patents cover our product candidates, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates. In addition, the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Any of these outcomes could have an adverse impact on our business.

If patent applications that we hold or in-license with respect to our technology or product candidates fail to issue, if their breadth or strength of protection is threatened, or if they fail to provide meaningful exclusivity for our product candidates, it could dissuade companies from collaborating with us. We have recently filed several patent applications covering our product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents, whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful challenge to these patents or any other patents owned by or exclusively licensed to us could deprive us of rights necessary for the successful commercialization of any product candidate that we or our collaborators may develop. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, if third parties have filed such patent applications, an interference proceeding in the United States can be initiated by the USPTO or a third party to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, we could become involved in derivation proceedings before the USPTO to determine inventorship with respect to our patent applications. We may also become involved in similar opposition proceedings in the European Patent Office or counterpart offices in other jurisdictions regarding our intellectual property rights. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent generally occurs 20 years after it is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical trials or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products. Any loss of patent protection could have a material adverse impact on our business. We may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates, which could harm our business and ability to achieve profitability.

If we are sued for infringing the intellectual property rights of third parties, such litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.

Our commercial success depends, in part, on us and our collaborators not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, inter partes reexamination and review

proceedings before the USPTO and corresponding non-US patent offices. Numerous US and non-US issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable.

Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, applications filed before November 29, 2000, and certain applications filed after that date that will not be filed outside the United States, remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. In addition, pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product candidates or their use or manufacture. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing such claims. If we are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving that a patent is invalid is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted, which could have a material adverse effect on us. If any issued third-party patents were held by a court of competent jurisdiction to cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until such patent expired. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. This could harm our business significantly.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates which may be impossible or require substantial time and monetary expenditure. We may also elect to enter into license agreements in order to settle patent infringement claims prior to litigation, and any such license agreement may require us to pay royalties and other fees that could be significant.

We may face claims that we misappropriated the confidential information or trade secrets of a third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using such trade secrets, which could limit our ability to develop our product candidates. We are not aware of any material threatened or pending claims related to these matters, but in the future litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in

substantial costs and be a distraction to management. During the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our or our licensors' intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in countries outside the United States, or from selling or importing infringing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our licensors have no issued patents and our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly, could put our and our licensors' patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and even if we or our licensors are successful the damages or other remedies awarded, if any, may not be commercially meaningful.

We have in-licensed a significant portion of our intellectual property from Amgen. If we breach any of our license agreements with Amgen, we could lose the ability to continue the development and potential commercialization of one or more of our product candidates.

We hold rights under a number of license agreements with Amgen that are important to our business. Our discovery and development platform is built, in part, around patents exclusively in-licensed from Amgen. These agreements generally grant us the exclusive (except as to the licenses to Amgen know-how, which are non-exclusive and limited as to their field of use), worldwide (except with regard to PINTA 745 in Japan, which was previously licensed to Takeda Pharmaceutical Company Limited) license to research, develop, improve, make, use, offer for sale, sell, import, export or otherwise exploit several classes of novel compounds, including PINTA 745 and STM 434. Under our existing license agreements, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales, as well as other material obligations. If there is any conflict, dispute, disagreement or issue of non-performance between us and Amgen regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations under any such agreement, we may be liable to pay damages and Amgen may have a right to terminate the affected license. The loss of any or all of our license agreements with Amgen could materially adversely affect our ability to proceed to utilize the affected intellectual property in our drug discovery and development efforts, and our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product candidates. The risks described elsewhere pertaining to our patents and other intellectual property rights also apply to the intellectual property rights that we license, and any failure by us or our licensors to obtain, maintain and enforce these rights could have a material adverse effect on our business.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business and on our stock price.

Third parties may infringe our patents, the patents of our licensors, or misappropriate or otherwise violate our or our licensors' intellectual property rights. Our and our licensors' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology. In the future, we or our licensors may elect to initiate legal proceedings to enforce or defend our or our licensors' intellectual property rights, to protect our or our licensors' trade secrets or to determine the validity or scope of intellectual property rights we own or control. Any claims that we assert against perceived infringers could also provoke these parties to assert counterclaims against us alleging that we infringe their intellectual property rights. In addition, third parties may initiate legal proceedings against us or our licensors to challenge the validity or scope of intellectual property rights we own or control. The proceedings can be expensive and time-consuming. Many of our or our licensors' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our licensors can. Accordingly, despite our or our licensors' efforts, we or our licensors may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own or control, particularly in countries where the laws may not protect our rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, in whole or in part, or may refuse to stop the other party from using the technology at issue on the grounds that our or our licensors' patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our or our licensors' patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Interference or derivation proceedings provoked by third parties, brought by us or our licensors or collaborators, or brought by the USPTO or any non-US patent authority may be necessary to determine the priority of inventions or other matters of inventorship with respect to our patents or patent applications. We may also become involved in other proceedings, such as re-examination or opposition proceedings, inter partes review or other preissuance or post-grant proceedings in the USPTO or its foreign counterparts relating to our intellectual property or the intellectual property rights of others. An unfavorable outcome in any such proceeding could require us or our licensors to cease using the related technology and commercializing our product candidates, or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our licensors a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our licensors. In addition, if the breadth or strength of protection provided by our or our licensors' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and it may distract our management and other employees. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent.

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 this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of shares of our common stock.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity, and obtaining and enforcing biopharmaceutical patents is costly, time-consuming, and inherently uncertain. The Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on future decisions by the US Congress, or Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or collaborators may obtain in the future.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to US patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of our or our licensors' issued patents, all of which could have a material adverse effect on our business and financial condition.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to competitors. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information 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, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the United States. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and major operators of dialysis and cancer clinics.

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community, including major operators of dialysis and cancer clinics. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

the efficacy and safety of such product candidates as demonstrated in clinical trials;

the clinical indications for which the product candidate is approved;
acceptance by physicians, major operators of cancer and dialysis clinics and patients of the drug as a safe and effective treatment;
the potential and perceived advantages of product candidates over alternative treatments;
the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
any restrictions on use together with other medications;
the prevalence and severity of any side effects;
product labeling or product insert requirements of the FDA or other regulatory authorities;
the timing of market introduction of our products as well as competitive products;
the cost of treatment in relation to alternative treatments;

the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
relative convenience and ease of administration; and
the effectiveness of our sales and marketing efforts and those of our collaborators.

If any of our product candidates are approved but fail to achieve market acceptance among physicians, patients, healthcare payors or major operators of dialysis and cancer clinics, we will not be able to generate significant revenues, which would compromise our ability to become profitable. In particular, the dialysis industry is dominated by two companies, DaVita Healthcare Partners and Fresenius Medical Care. In the event PINTA 745 fails to be accepted by either of these companies, our ability to generate revenues from PINTA 745 and become profitable would be adversely affected.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the United States and in other countries in which we seek to commercialize our products, which could harm our business.

Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors in the United States often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Recently enacted and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In particular, all Medicare payments for dialysis treatments to ESRD patients are now made under a single bundled payment rate that provides a fixed payment rate to encompass all goods and services provided during the dialysis treatment, including pharmaceuticals that were historically separately reimbursed to the dialysis providers, irrespective of the level of pharmaceuticals administered or additional services performed. Most lab services that used to be paid directly to laboratories are also included in the bundled payment. Unless we are able to secure an exemption, PINTA 745 may be subject to the bundled payment system. In recent years, Congress has considered further reductions in Medicare reimbursement for drugs administered by physicians. The Center for Medicare and Medicaid Services, or CMS, the agency that runs the Medicare program, also has the authority to revise reimbursement rates, including under the bundled payment system, and to implement coverage restrictions for some drugs. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price we can receive for those products. While the Medicare Modernization Act and Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, or the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. The Affordable Care Act expanded manufacturers' rebate liability to include covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price, or AMP, to 23.1% of AMP, and capped the total rebate amount for innovator drugs at 100% of AMP. The Affordable Care Act and subsequent legislation also changed the definition of AMP. Furthermore, the Affordable Care Act imposes a significant annual, nondeductible fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. Although it is too early to determine the effect of the Affordable Care Act, it appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. More recently, in August 2011, the President signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2% Medicare reductions went into effect. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or

interpretations will be changed, or what the impact of such changes on the regulatory approvals of our product candidates, if any, may be.

In the United States, the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Furthermore, the increased emphasis on managed healthcare in the United States and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions for our current and future product candidates. Our commercial opportunities will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any products that we may develop. Competition could result in reduced sales and pricing pressure on our product candidates, if approved, which in turn would reduce our ability to generate meaningful revenues and have a negative impact on our results of operations. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

Products are currently marketed or used off-label for the muscle wasting-related indications for which the products in our pipeline are being developed, and a number of companies are or may be developing new treatments for muscle wasting indications. These products, as well as promotional efforts by competitors and clinical trial results of competitive products, could significantly diminish any ability to market and sell PINTA 745 and other product candidates focused on muscle wasting-related indications. Today’s treatment for protein-energy wasting and cancer cachexia often involves the administration of readily available nutritional supplements and appetite stimulants including, in some jurisdictions, medical marijuana. In addition, there are two commercially available steroids, nandrolone and oxandrolone, that are sometimes prescribed off-label for the treatment of weight loss in cancer patients. A number of companies are developing drug candidates for muscle wasting applications, including: Eli Lilly & Co., which is conducting Phase 1 clinical studies and Phase 2 clinical trials for LY2495655, and Pfizer Inc., which is conducting Phase 1 clinical studies for PF-06252616, both of which are myostatin antibodies, to evaluate their ability to increase and improve muscle mass in various patient populations; Novartis Corporation, which is conducting Phase 1 clinical studies and Phase 2 clinical trials for BYM338, an ActR2B antibody, to evaluate its ability to build muscle in patients with various muscle-wasting conditions; Ligand Pharmaceuticals, which is developing LGD-4033, a selective androgen receptor modulator, for muscle wasting; Regeneron Pharmaceuticals, Inc., which is developing REGN1033, a myostatin antibody, in collaboration with Sanofi-Aventis; and GTx, Inc., which is developing ostarine, a selective androgen receptor modulator for cachexia.

There are numerous approved products and therapies for ovarian cancer, and a number of companies are or may be developing new treatments for ovarian cancer and other solid tumors. These therapies, as well as promotional efforts by competitors and clinical trial results of competitive products, could significantly diminish any ability to market and

sell STM 434. Approved drug therapies for ovarian cancer include chemotherapy with platinum compounds such as cisplatin or carboplatin and taxane compounds such as paclitaxel or docetaxel, and hormone therapies including gosarelin, luprolide, tamoxifen, letrozole, anostrazole and exemestane. A number of companies are developing drug candidates for ovarian cancer and other solid tumors, including Genentech/Roche, which is developing bevacizumab (Avastin) and other potential drug therapies.

Many of these approved drugs and therapies for muscle wasting and ovarian cancer are well-established and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and other drugs and nutritional supplements are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. We expect that if either PINTA 745 or STM 434 is approved, it will be priced at a significant premium over competitive generic products. This pricing premium may make it difficult for us to differentiate these products from currently approved or commonly used therapies and impede adoption of our product, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development.

Many of our competitors or potential competitors have significantly greater established presence in the market, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to obtain patent protection or other intellectual property rights, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or non-competitive before we can recover the expenses of development and commercialization.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We do not currently have an organization for the sale, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate product revenues and may not become profitable. We will be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without an internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies. If we are not successful in commercializing our current or future product candidates either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2014, we had 15 employees. As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we will need additional managerial, operational, manufacturing, sales, marketing, financial and other resources. Our management, personnel and systems currently in place may not be adequate to support this future growth. Future growth would impose significant added responsibilities on members of

management, including:

- managing our clinical studies and trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational and finance systems; and
- expanding our facilities.

As our operations expand, we will need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical studies and trials effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully growing our company.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel.

We are highly dependent upon our personnel, including Isaac E. Ciechanover, M.D., our President, Chief Executive Officer and founder, and Christopher Haqq, Ph.D., M.D., our Chief Medical Officer. Our employment agreements with Drs. Ciechanover and Haqq are at-will and do not prevent them from terminating their employment with us at any time. The loss of the services of either of them could impede the achievement of our research, development and commercialization objectives.

Our future growth and success depend on our ability to recruit, retain, manage and motivate our employees. The loss of any member of our senior management team or the inability to hire or retain experienced management personnel could compromise our ability to execute our business plan and harm our operating results. Because of the specialized scientific and managerial nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute will constrain our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, 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, or in return for, 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 a federal healthcare program such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for 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;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also created federal criminal laws that prohibit knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal physician sunshine requirements under the Affordable Care Act requires manufacturers of drugs, devices, biologics and medical supplies to report annually to HHS information related to payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members and applicable group purchasing organizations; and
- analogous state and foreign 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; 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 and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare 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, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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 clinical trials and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical trials, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could 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;
termination of clinical trial sites or entire trial programs;
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 subjects or patients;
loss of revenue;
diversion of management and scientific resources from our business operations; and
the inability to commercialize any products that we may develop.

We currently hold $5.0 million in product liability insurance coverage in the aggregate, which we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which

may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

If we and our third-party manufacturers 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 and our third-party manufacturers 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 or our third-party manufacturers' 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 with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, 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 or hazardous 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.

Our business and operations would suffer in the event of computer system failures or security breaches.

Our internal computer systems, and those of our CROs and other business vendors on which we rely, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, fire, terrorism, war and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and our business could be otherwise adversely affected.

Business disruptions could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our operations could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or manmade disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of product candidates could be disrupted, if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. The ultimate impact on us, our significant suppliers and our general infrastructure is unknown, but our operations and financial condition could suffer in the event of a major earthquake,

fire or other natural disaster.

Risks Related to Ownership of Our Common Stock

Our stock price has been and will likely continue to be volatile and may decline regardless of our operating performance.

The market price of shares of our common stock has been, and will likely to continue to be, subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this “Risk Factors” section, these factors include:

the success of competitive products or technologies;
regulatory actions with respect to our product candidates or products or our competitors’ product candidates or products;
actual or anticipated changes in our growth rate relative to our competitors;
announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
results of clinical trials of our product candidates or those of our competitors;

regulatory or legal developments in the United States and other countries;
developments or disputes concerning patent applications, issued patents or other proprietary rights;
the recruitment or departure of key personnel;
the level of expenses related to any of our product candidates or clinical development programs;
the results of our efforts to in-license or acquire additional product candidates or products;
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;
fluctuations in the valuation of companies perceived by investors to be comparable to us;
inconsistent trading volume levels of our shares;
announcement or expectation of additional financing efforts;
sales of our common stock by us, our insiders or our other stockholders;
changes in the structure of healthcare payment systems;
market conditions in the pharmaceutical and biotechnology sectors; and
general economic, industry and market conditions.

In addition, the stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of these risks or any of a broad range of other risks, including those described in these “Risk Factors,” could have a dramatic and material adverse impact on the market price of our common stock.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock may be volatile, and in the past companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of the closing of our initial public offering in October 2014, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates together owned more than 80% of our outstanding voting stock, assuming no exercise of outstanding options. These stockholders may be able to determine the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

After the lock-up agreements pertaining to our initial public offering expire, an additional 16,126,604 shares will be eligible for sale in the public market. In addition, 180 days after the completion of our public offering, holders of approximately 14,193,659 shares of our common stock will have the right to require us to register those shares under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to a registration rights agreement. If our existing shareholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no

relationship between such sales and the performance of our business.

We are an “emerging growth company” and we intend to take advantage of reduced disclosure and governance requirements applicable to emerging growth companies, which could result in our common stock being less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company, which in certain circumstances could be for up to five years. We will cease to be an “emerging growth company” upon the earliest of: (1) the last day of the fiscal year following the fifth anniversary of the consummation of our initial public offering, (2) the last day of the first fiscal year in which our annual gross revenues are $1 billion or more, (3) the date on which we have, during the previous rolling three-year period, issued more than $1 billion in non-convertible debt securities, and (4) the date on which we are deemed to be a “large accelerated filer” as defined in the Exchange Act.

Our status as an “emerging growth company” under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an “emerging growth company” we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our financial accounting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

We have incurred and will continue to incur increased costs as a result of being a public company and our management expects to devote substantial time to public company compliance programs.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley, as well as rules subsequently adopted by the SEC, and The NASDAQ Global Select Market to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC to adopt additional rules and regulations in these areas, such as mandatory “say on pay” voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

The rules and regulations applicable to public companies have substantially increased our legal and financial compliance costs and make some activities more time-consuming and costly. To the extent these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse

effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any material weaknesses or if we fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with US generally accepted accounting principles. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Prior to the closing of our initial public offering in October 2014, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting. During the course of preparing for the offering, we determined that we had a material weakness in our internal control over financial reporting as of December 31, 2012 and 2013 relating to the design and operation of our closing and financial reporting processes.

For a discussion of our remediation plan and the actions that we have executed during 2014, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Internal Control over Financial Reporting.” The actions we have taken are subject to continued review, supported by confirmation and testing by management as well as audit committee oversight. While we have implemented a plan to remediate this weakness, we cannot assure you that we will be able to remediate this weakness, which could impair our ability to accurately and timely report our financial position, results of operations or cash flows. If we are unable to successfully remediate this material weakness, and if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with applicable NASDAQ listing requirements.

Our failure to remediate the material weakness identified above or the identification of additional material weaknesses in the future, could adversely affect our ability to report financial information, including our filing of quarterly or annual reports with the SEC on a timely and accurate basis. Moreover, our failure to remediate the material weakness identified above or the identification of additional material weaknesses could prohibit us from producing timely and accurate financial statements, which may adversely affect our stock price and we may be unable to maintain compliance with NASDAQ listing requirements.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of potential gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of October 31, 2014, we have outstanding 20,212,889 shares of common stock. Of these shares, 3,637,968 shares of common stock are freely tradeable in the public market, without restriction. Of the remaining shares, 16,126,604 shares of our common stock are restricted as a result of securities laws or lock-up agreements but will be able to be sold after the 180-day contractual lock-up and other legal restrictions on resale lapse. We cannot predict the effect, if any, that public sales of these shares or the availability of these shares for sale will have on the market price of our common stock.

In addition, 180 days after the completion of our public offering, holders of approximately 14,193,659 shares of our common stock will have the right, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also have registered 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. On May 15, 2015, up to approximately 350,000 shares of common stock subject to RSUs will settle, of which a portion may be sold in the open market. If our existing shareholders sell substantial amounts of our common stock in the public market, or if the public perceives that such sales could occur, this could have an adverse impact on the market price of our common stock, even if there is no relationship between such sales and the performance of our business.

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

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise capital, we may sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares issued in connection with acquisitions, if any, may result in material dilution to our investors. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our directors, executive officers and other employees and service providers, including officers, employees and service providers of our subsidiaries. Future grants of RSUs, options and other equity awards and issuances of common stock under our equity incentive plans may have an adverse effect on the market price of our common stock.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders, or remove our current management. These include provisions that will:

- permit our board of directors to issue up to 20,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate;
- provide that all vacancies on our board of directors, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;
- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election; and
- provide that special meetings of our stockholders may be called only by the board of directors or by such person or persons requested by a majority of the board of directors to call such meetings.

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, who are responsible for appointing the members of our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may discourage, delay or prevent someone from acquiring us or merging with us whether or not it is desired by or beneficial to our stockholders. Under Delaware law, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other things, the board of directors has approved the transaction. Any provision of our amended and restated certificate of incorporation or amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail

to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Recent Sales of Unregistered Equity Securities

In October 2014, upon the closing of our initial public offering, all 12,298,515 shares of our then-outstanding redeemable convertible preferred stock were automatically converted into 12,298,515 shares of common stock. The issuance of such shares of common stock was exempt from the registration requirements of the Securities Act, pursuant to Section 3(a)(9) and Section 4(s) of the Securities Act.

In September 2014, we issued 59,761 shares of common stock to Memorial Sloan Kettering Cancer Center in connection with the execution of an exclusive option agreement. The issuance of such securities was exempt from the registration requirements of the Securities Act pursuant to Section 4(a)(2) of the Securities Act, as a transaction by the issuer not involving a public offering.

During the three months ended September 30, 2014, we issued RSUs for 6,000 shares of common stock and options to purchase 209,959 shares of common stock to our employees, directors and consultants. The issuance of such securities was exempt from the registration requirements of the Securities Act pursuant to Rule 701, as offers and sales of securities pursuant to certain compensatory benefit plans and contracts relating to compensation.

Use of Proceeds

In October 2014, we completed our initial public offering in which 5,750,000 shares of our common stock (including 750,000 shares from the full exercise by the underwriters of their option to purchase additional shares) were sold at a price to the public of $11.00 per share, resulting in gross proceeds of $63.3 million to the Company. All of the shares issued and sold in the offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No.333-196936), which was declared effective by the SEC on October 15, 2014. Goldman Sachs & Co. and Citigroup Global Markets, Inc. acted as joint book-running manager of the offering and as representatives of the underwriters. Jeffries Group Inc. acted as co-manager for the offering. Following the sale of the shares in connection with the closing of our initial public offering, the offering terminated.

We received aggregate net proceeds from the offering of approximately $55.8 million, after deducting approximately $4.5 million of underwriting discounts and commissions and offering-related expenses estimated to be approximately $3.0 million.

No offering costs were paid directly or indirectly to any of our directors or officers or persons owning ten percent or more of our common stock or to any other affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service. There has been no material change in the planned use of proceeds from our initial public offering as described in the final prospectus dated October 15, 2014 and filed with the Securities and Exchange Commission on October 16, 2014.

Item 3. Defaults Upon Senior Securities
None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits.

Exhibit No.	Description of Exhibit	Incorporated by Reference Form	File No.	Exhibit	Filing Date	Filed Herewith
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.2	6/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	6/20/2014	
4.1	Form of Atara Biotherapeutics, Inc. Common Stock Certificate.	S-1/A	333-196936	4.1	7/10/2014	
4.2	Investor Rights Agreement of Atara Biotherapeutics, Inc., dated March 31, 2014.	S-1	333-196936	4.2	6/20/2014	
10.1+	Atara Biotherapeutics, Inc. 2014 Equity Incentive Plan.	S-1/A	333-196936	10.1	7/10/2014	
10.2+	Atara Biotherapeutics, Inc. 2014 Employee Stock Purchase Plan.	S-1	333-196936	10.8	6/20/2014	
10.3	Sublease Agreement, by and between Atara Biotherapeutics, Inc. and Accesia, Inc., dated September 11, 2014.	S-1/A	333-196936	10.28	9/26/2014	
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1(1)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					
101.SCH	XBRL Schema Document					
101.CAL	XBRL Calculation Linkbase Document					
101.LAB	XBRL Labels Linkbase Document					
101.PRE	XBRL Presentation Linkbase Document					

101.DEF XBRL Definition Linkbase Document.

+Indicates management contract or compensatory plan.

(1) The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, Atara Biotherapeutics, Inc. has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ATARA
BIOTHERAPEUTICS,
INC.

Date: November 12, 2014

By:/s/ Isaac Ciechanover
Isaac Ciechanover
President and Chief
Executive Officer
(Duly Authorized Officer
and Principal
Executive Officer)

By:/s/ John McGrath
John McGrath
Chief Financial Officer
(Duly Authorized Officer
and Principal
Financial and Accounting
Officer)

Index to Exhibits

Exhibit		Incorporated by Reference				Filed
No.	Description of Exhibit	Form	File No.	Exhibit	Filing Date	Herewith
3.1	Amended and Restated Certificate of Incorporation of Atara Biotherapeutics, Inc.	S-1	333-196936	3.2	6/20/2014	
3.2	Amended and Restated Bylaws of Atara Biotherapeutics, Inc.	S-1	333-196936	3.4	6/20/2014	
4.1	Form of Atara Biotherapeutics, Inc. Common Stock Certificate.	S-1/A	333-196936	4.1	7/10/2014	
4.2	Investor Rights Agreement of Atara Biotherapeutics, Inc., dated March 31, 2014.	S-1	333-196936	4.2	6/20/2014	
10.1+	Atara Biotherapeutics, Inc. 2014 Equity Incentive Plan.	S-1/A	333-196936	10.1	7/10/2014	
10.2+	Atara Biotherapeutics, Inc. 2014 Employee Stock Purchase Plan.	S-1	333-196936	10.8	6/20/2014	
10.3	Sublease Agreement, by and between Atara Biotherapeutics, Inc. and Accesia, Inc., dated September 11, 2014.	S-1/A	333-196936	10.28	9/26/2014	
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1(1)	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C Section 1350 as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document					
101.SCH	XBRL Schema Document					
101.CAL	XBRL Calculation Linkbase Document					
101.LAB	XBRL Labels Linkbase Document					

101.PRE XBRL Presentation Linkbase Document

101.DEF XBRL Definition Linkbase Document.

+Indicates management contract or compensatory plan.

(1) The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.