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

FORM 10-Q

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

For the quarterly period ended June 30, 2016

or

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

For the transition period from _____ to _____

Commission File No. 001-37852

PROTAGONIST THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**98-0505495**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
521 Cottonwood Drive, Suite 100 Milpitas, California 95035	**(408) 649-7370**
(Address, including zip code, of registrant's principal executive offices)	**(Telephone number, including area code, of registrant's principal executive offices)**

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act of 1934). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

Class	Outstanding at August 31, 2016
Common Stock, $0.00001 par value	**16,461,481**

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PART I. – FINANCIAL INFORMATION
ITEM 1. FINANCIAL STATEMENTS

PROTAGONIST THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share data)

	June 30, 2016	December 31, 2015
Assets	(Unaudited)	(Note 2)
Current assets:		
Cash and cash equivalents	$ 13,768	$ 4,055
Restricted cash	10	10
Available-for-sale securities	6,408	7,868
Research and development tax incentive receivable	1,744	715
Prepaid expenses and other current assets	487	1,558
Total current assets	22,417	14,206
Property and equipment, net	599	609
Deferred offering costs	1,466	—
Other assets	34	30
Total assets	$ 24,516	$ 14,845
Liabilities Redeemable Convertible Preferred Stock and Stockholders' Deficit		
Current liabilities:		
Accounts payable	$ 1,441	$ 1,247
Accrued expenses and other payables	2,669	1,879
Total current liabilities	4,110	3,126
Redeemable convertible preferred stock tranche liability	—	1,643
Redeemable convertible preferred stock warrant liability	—	480
Total liabilities	4,110	5,249
Commitments and contingencies		
Redeemable convertible preferred stock, $0.00001 par value: 126,374,911 shares authorized; 124,374,909 and 77,185,117 shares issued and outstanding as of June 30, 2016 (unaudited) and December 31, 2015, respectively; redemption value of $65,038 and $41,538 as of June 30, 2016 (unaudited) and December 31, 2015, respectively	66,610	36,996
Stockholders' deficit:		
Common stock, $0.00001 par value, 160,000,000 shares authorized; 383,910 and 272,409 shares issued and outstanding as of June 30, 2016 (unaudited) and December 31, 2015, respectively	—	—
Additional paid-in capital	158	118
Accumulated other comprehensive loss	(101)	(102)
Accumulated deficit	(46,261)	(27,416)
Total stockholders' deficit	(46,204)	(27,400)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 24,516	$ 14,845

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PROTAGONIST THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 5,696	$ 2,297	$ 11,321	$ 4,480
General and administrative	1,395	786	2,810	1,292
Total operating expenses	7,091	3,083	14,131	5,772
Loss from operations	(7,091)	(3,083)	(14,131)	(5,772)
Interest income	27	—	39	1
Change in fair value of redeemable convertible preferred stock tranche and warrant liabilities	—	(136)	(4,719)	(145)
Other expense	(34)	—	(34)	—
Net loss	$ (7,098)	$ (3,219)	$ (18,845)	$ (5,916)
Net loss attributable to common stockholders	$ (7,323)	$ (3,219)	$ (19,110)	$ (5,916)
Net loss per share attributable to common stockholders, basic and diluted	$ (19.07)	$ (13.78)	$ (56.90)	$ (25.55)
Weighted-average shares used to compute net loss per share attributable to common stockholders, basic and diluted	383,910	233,531	335,855	231,518

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PROTAGONIST THERAPEUTICS, INC.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited)
(In thousands)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net loss	$(7,098)	$(3,219)	$(18,845)	$(5,916)
Other comprehensive loss:				
Loss on translation of foreign operations,	(4)	(26)	(2)	(42)
Unrecognized gain (loss) on available-for-sale securities	(1)	—	4	—
Comprehensive loss	$(7,103)	$(3,245)	$(18,843)	$(5,958)

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PROTAGONIST THERAPEUTICS, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Six Months Ended June 30,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(18,845)	$(5,916)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	159	111
Loss on disposal of property and equipment	34	—
Amortization of premium on available-for-sale securities	72	—
Stock-based compensation	162	40
Change in fair value associated with redeemable convertible preferred stock tranche liability	4,194	—
Change in fair value of redeemable convertible preferred stock warrant liability	525	145
Changes in operating assets and liabilities:		
Research and development tax credit receivable	(1,030)	(173)
Prepaid expenses and other current assets	1,134	(70)
Other assets	(4)	—
Accounts payable	85	160
Accrued expenses and other payables	202	(174)
Net cash used in operating activities	(13,312)	(5,877)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(279)	(66)
Purchase of available-for-sale securities	(6,396)	—
Proceeds from maturities of available-for-sale securities	7,788	—
Net cash provided by (used in) investing activities	1,113	(66)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	22,508	—
Proceeds from issuance of common stock upon exercise of stock options	143	57
Payments of deferred offering costs	(770)	—
Net cash provided by financing activities	21,881	57
Effect on exchange rate changes on cash and cash equivalents	31	(39)
Net increase (decrease) in cash and cash equivalents	9,713	(5,925)
Cash and cash equivalents, beginning of period	4,055	9,324
Cash and cash equivalents, end of period	$ 13,768	$ 3,399
SUPPLEMENTAL DISCLOSURES OF NON-CASH FINANCING INFORMATION:		
Settlement of fair value of redeemable convertible preferred stock liability	$ 5,837	$ —
Accretion of redeemable convertible preferred stock	$ 265	$ —
Deferred offering costs in accounts payable and accrued liabilities	$ 696	$ —
Reclassification of preferred stock warrant liability to equity	$ 1,005	$ —

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

PROTAGONIST THERAPEUTICS, INC.
Notes to Unaudited Condensed Consolidated Financial Statements

1. Organization and Description of Business

Protagonist Therapeutics, Inc. (the "Company") was incorporated in the state of Delaware on August 22, 2006 and is headquartered in Milpitas, California. The Company is a clinical-stage biopharmaceutical company with a proprietary peptide technology platform focused on discovering and developing new chemical entities to address significant unmet medical needs.

Protagonist Pty Ltd is a wholly-owned subsidiary located in Brisbane, Australia. The Company manages its operations as a single operating segment.

Reverse Stock Split

In July 2016, the Company's board of directors approved an amendment to the Company's amended and restated certificate of incorporation to effect a reverse split of the Company's issued and outstanding common stock at a 1-for-14.5 ratio, which was effected on August 11, 2016. The par value and authorized shares of common stock and convertible preferred stock were not adjusted as a result of the reverse split. All issued and outstanding common stock, options to purchase common stock and per share amounts contained in the condensed consolidated financial statements have been retroactively adjusted to reflect the reverse stock split for all periods presented.

Initial Public Offering

On August 10, 2016, the Company's registration statement on Form S-1 (File No. 333-212476) relating to its initial public offering ("IPO") of common stock became effective. The IPO closed on August 16, 2016 at which time the Company issued 7,500,000 shares of its common stock at a price of $12.00 per share. The Company received $83.7 million, net of underwriting discounts and commissions, but before deducting offering costs. In addition, upon closing the IPO, all outstanding shares of the redeemable convertible preferred stock converted into 8,577,571 shares of common stock and there are no shares of redeemable convertible preferred stock outstanding. In September 2016, the Company issued an additional 252,972 shares of common stock at a price of $12.00 per share following the underwriters' exercise of their option and received proceeds of $2.8 million, net of underwriting discounts and commissions.

2. Summary of Significant Accounting Policies

Basis of Preparation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") and applicable rules and regulations of the Securities and Exchange Commission ("SEC") regarding interim financial reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by GAAP have been condensed or omitted, and accordingly the balance sheet as of December 31, 2015 has been derived from the audited consolidated financial statements at that date but does not include all of the information required by GAAP for complete consolidated financial statements. These unaudited interim condensed consolidated financial statements have been prepared on the same basis as the Company's annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting only of normal recurring adjustments) that are necessary for a fair statement of the Company's consolidated financial information. The results of operations for the three and six months ended June 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016 or for any other interim period or for any other future year.

The accompanying interim unaudited condensed consolidated financial statements and related financial information should be read in conjunction with the audited consolidated financial statements and the related notes thereto for the year ended December 31, 2015 included in the Company's prospectus, filed with the SEC on August 12, 2016, pursuant to Rule 424(b) under the Securities Act.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

Principles of Consolidation

The accompanying unaudited interim condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All significant intercompany transactions and balances have been eliminated upon consolidation.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the condensed consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including those related to accruals for research and development activities, fair value of redeemable convertible preferred stock tranche liability, fair value of redeemable convertible preferred stock warrant liability, fair value of common stock, stock-based compensation and income taxes. Management bases these estimates on historical and anticipated results, trends, and various other assumptions that the Company believes are reasonable under the circumstances, including assumptions as to future events. Actual results may differ from those estimates.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash, cash equivalents and available-for-sale securities. Substantially all the Company's cash is held by one financial institution that management believes is of high credit quality. Such deposits may, at times, exceed federally insured limits.

Cash Equivalents

Cash equivalents that are readily convertible to cash are stated at cost, which approximates market value. The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market funds.

Restricted Cash

Restricted cash consisted of cash balances primarily held as security in connection with the Company's corporate credit card.

Available-for-Sale Securities

All marketable securities, have been classified as "available-for-sale" and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. Short-term marketable securities have maturities less than 365 days as of the balance sheet date. Long-term marketable securities have maturities greater than 365 days as of the balance sheet date. Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest income. The cost of securities sold is based on the specific-identification method. Interest on marketable securities is included in interest income.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

Deferred Offering Costs

Deferred offering costs, which include legal, accounting, printer and filing fees, related to the IPO are capitalized. The deferred offering costs will be offset against proceeds from the IPO, to be recorded in the quarter ended September 30, 2016. As of June 30, 2016, $1.5 million of deferred offering costs were capitalized on the accompanying condensed consolidated balance sheet. There were no such costs capitalized as of December 31, 2015.

Fair Value of Financial Instruments

Fair value accounting is applied for all financial assets and liabilities that are recognized or disclosed at fair value in the condensed consolidated financial statements on a recurring basis (at least annually). The carrying amount of the Company's financial instruments, including cash equivalents, accounts payable and accrued expenses and other payables approximate fair value due to their short term maturities. See Note 3. Fair Value Measurements regarding the fair value of the Company's available-for-sale securities, redeemable convertible preferred stock tranche liability and redeemable convertible preferred stock warrant liability.

Accrued Research and Development Costs

The Company accrues for estimated costs of research and development activities conducted by third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and include these costs in accrued liabilities in the condensed consolidated balance sheets and within research and development expense in the condensed consolidated statements of operations. These costs are a significant component of the Company's research and development expenses. The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred. However, the status and timing of actual services performed, number of patients enrolled, and the rate of patient enrollments may vary from the Company's estimates, resulting in adjustments to expense in future periods. Changes in these estimates that result in material changes to the Company's accruals could materially affect the Company's results of operations.

Research and Development Costs

Research and development costs are expensed as incurred and consist of salaries and benefits, stock-based compensation expense, lab supplies and facility costs, as well as fees paid to others that conduct certain research and development activities on the Company's behalf.

Research and Development Incentive Grant

The Company is eligible under the AusIndustry research and tax development tax incentive program to obtain a cash amount from the Australian Taxation Office ("ATO"). The tax incentive is available to the Company on the basis of specific criteria with which the Company must comply. Specifically, the Company must have revenue of less than AUD 20.0 million and cannot be controlled by income tax exempt entities. These research and development tax incentives are recognized as contra research and development expense when the right to receive has been attained and funds are considered to be collectible. The tax incentive is denominated in Australian dollars and, therefore, the related receivable is remeasured into U.S. dollars as of each reporting date.

Under certain conditions, research and development activities conducted outside Australia ("overseas finding") also qualify for the research and development incentive grant. Funds received for overseas finding are at a risk of clawback until substantiation that less than 50% research and development expenditures for a project will be incurred overseas. A deferred tax incentive is recorded upon the cash receipt of the overseas finding funds and a reduction of research and development expense is not recognized until the Company can substantiate that more than 50% of the total project expenditure will occur in Australia.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period, without consideration of potentially dilutive securities. The net loss attributable to common stockholders is calculated by adjusting the net loss of the Company for the accretion on the redeemable convertible preferred stock. Diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders for all periods presented since the effect of potentially dilutive securities are anti-dilutive given the net loss of the Company.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, which is intended to provide financial statement users with more useful information about expected credit losses on financial assets held by a reporting entity at each reporting date. The new standard replaces the existing incurred loss impairment methodology with a methodology that requires consideration of a broader range of reasonable and supportable forward-looking information to estimate all expected credit losses. This ASU is effective for fiscal years and interim periods within those years beginning after December 15, 2019 and early adoption is permitted for fiscal years and interim periods within those years beginning after December 15, 2018. The Company is currently evaluating the impact of this new guidance.

3. Fair Value Measurements

Financial assets and liabilities are recorded at fair value. The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1—Inputs are unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted market prices included in Level 1) are either directly or indirectly observable for the asset or liability through correlation with market data at the measurement date and for the duration of the instrument's anticipated life.

Level 3—Inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model.

In determining fair value, the Company utilizes quoted market prices, broker or dealer quotation, or valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible as well as considers counterparty credit risk in its assessment of fair value.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

The following table presents the fair value of the Company's financial assets and liabilities determined using the inputs defined above (amounts in thousands).

	June 30, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$12,032	$ —	$ —	$12,032
Corporate bonds	—	3,318	—	3,318
Commercial paper	—	3,693	—	3,693
Total financial assets	$12,032	$7,011	$ —	$19,043

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds	$2,136	$ —	$ —	$ 2,136
Corporate bonds	—	7,368	—	7,368
Commercial paper	—	500	—	500
Total financial assets	$2,136	$7,868	$ —	$10,004
Liabilities:				
Redeemable convertible preferred stock tranche liability	$ —	$ —	$1,643	$ 1,643
Redeemable convertible preferred stock warrant liability	—	—	480	480
Total financial liabilities	$ —	$ —	$2,123	$ 2,123

The corporate bonds and commercial paper are classified as Level 2 as they were valued based upon quoted market prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets.

Level 3 instruments are valued based on unobservable inputs that are supported by little or no market activity and reflect the Company's assumptions in measuring fair value. The fair value measurements of the redeemable convertible preferred stock tranche liability and the redeemable convertible preferred stock warrant liability were based on significant inputs not observed in the market and thus represent a Level 3 measurement.

The redeemable convertible preferred stock tranche liability stems from the initial sale of the Company's Series C redeemable convertible preferred stock wherein the Company was obligated to sell additional shares in subsequent closings contingent upon a majority of the stockholders of the outstanding redeemable convertible preferred stock and/or the achievement of certain development milestones. The subsequent closings were deemed to be freestanding financial instruments that were at the option of the holders. The Company estimates the fair value of this liability using a one-step binomial lattice model in combination with Option Pricing Model. The change in fair value is recognized as a gain or loss in the condensed consolidated statements of operations. See Note 10 for further discussion on the redeemable convertible preferred stock tranche liability and related valuations.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

The determination of the fair value of the redeemable convertible preferred stock warrant liability is discussed in Note 8. Generally, increases or decreases in the fair value of the underlying redeemable convertible preferred stock would result in a directionally similar impact in the fair value measurement of the warrant liability.

The following table sets forth a summary of the changes in the fair value of the Company's Level 3 financial instruments as follows (in thousands):

Redeemable Convertible Preferred Stock Tranche Liability:	
Balance at December 31, 2015	$ 1,643
Change in fair value upon revaluation	4,194
Settlement of redeemable convertible preferred stock tranche liability due to issue of Series C redeemable convertible preferred shares	(5,837)
Balance at June 30, 2016	$ —
Redeemable Convertible Preferred Stock Warrant Liability:	
Balance at December 31, 2015	$ 480
Change in fair value upon revaluation	525
Reclassification of redeemable convertible preferred stock warrant liability to redeemable convertible preferred stock	(1,005)
Balance at June 30, 2016	$ —

4. Balance Sheet Components

Cash Equivalents and Available-for-sale Securities

Cash equivalents and available-for-sale securities consisted of the following (in thousands):

	June 30, 2016			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 12,032	$ —	$ —	$ 12,032
Corporate bonds	3,319	—	(1)	3,318
Commercial paper	3,693	—	—	3,693
Total cash equivalents and available-for-sale securities	$ 19,044	$ —	$ (1)	$ 19,043
Classified as:				
Cash equivalents				$ 12,635
Available-for-sale securities				6,408
Total cash equivalents and available-for-sale securities				$ 19,043

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Money market funds	$ 2,136	$ —	$ —	$ 2,136
Corporate bonds	7,373	—	(5)	7,368
Commercial paper	500	—	—	500
Total cash equivalents and available-for-sale securities	$ 10,009	$ —	$ (5)	$ 10,004
Classified as:				
Cash equivalents				$ 2,136
Available-for-sale securities				7,868
Total cash equivalents and available-for-sale securities				$ 10,004

All available-for-sale securities held as of June 30, 2016 and December 31, 2015 had contractual maturities of less than one year. There have been no material realized gains or losses on available-for-sale securities for the periods presented.

Accrued expenses and Other Payables

Accrued liabilities and other payables consisted of the following (in thousands):

	June 30, 2016	December 31, 2015
Accrued contract research	$ 980	$ 976
Accrued employee related expenses	695	754
Accrued professional services fees	735	64
Accrued expenses and other payables	259	85
Total accrued liabilities	$ 2,669	$ 1,879

5. Research Collaboration and License Agreement

In October 2013, the Company's former collaboration partner decided to abandon a collaboration program with the Company and, pursuant to the terms of the agreement between the Company and the former collaboration partner, the Company elected to assume the responsibility for the development and commercialization of the product. Upon the former collaboration partner's abandonment, it assigned to the Company certain intellectual property arising from the collaboration and also granted the Company an exclusive license to certain background intellectual property rights of the former collaboration partner that relate to the products assumed by the Company. Upon the nomination of PTG-300 as a development candidate, the Company owed the former collaboration partner a payment of $250,000. If the Company initiates a Phase 1 clinical trial for PTG-300, it will pay the former collaboration partner an additional $250,000. The Company has the right, but not the obligation, to further develop and commercialize the products and, if the Company successfully develops and commercializes PTG-300 without a partner, the Company will pay to the former collaboration partner up to an additional aggregate of $128.5 million for the achievement of certain development, regulatory and sales milestone events. In addition, the Company will pay to the former collaboration partner a low single digit royalty on worldwide net sales of the product until the later of ten years from the first commercial sale of the product or the expiration of the last patent covering the product. For the three and six months ended June 30, 2016, the Company recorded research and development expense of zero and $250,000 under this agreement. There were no such costs incurred for the three and six months ended June 30, 2015.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

6. Government Grants

Research and Development Tax Incentive

The Company recognized AUD 666,000 ($498,000) and AUD 1.4 million ($1.0 million), and AUD 143,000 ($110,000) and AUD 270,000 ($210,000) as a reduction of research and development expenses for the three and six months ended June 30, 2016 and 2015, respectively, in connection with the Research and Development Tax Incentive from Australia. As of June 30, 2016 and December 31, 2015, the research and development tax credit receivable was AUD 2.4 million ($1.7 million) and AUD 978,000 ($715,000), respectively. In March 2016, the Company received AUD 237,000 ($176,000) for overseas findings and recorded the funds as deferred revenue in accrued expenses and other payables on the condensed consolidated balance sheet due to the possibility that the funds could have to be repaid.

SBIR Grant

In September 2015, the Company was awarded a Phase 1 SBIR Grant from the National Institute of Diabetes and Digestive and Kidney Diseases of the NIH in support of research on orally stable peptide antagonists of the interleukin-23 receptor ("IL-23R") as potential treatments for inflammatory bowel diseases ("IBD"). The Company recognizes contra research and development when expenses related to the grant have been incurred and the grant funds become contractually due from NIH. The total grant award was $224,000 and is for the period from September 2015 to August 2016. The Company recorded zero and $69,000 as a reduction of research and development expenses for the three and six months ended June 30, 2016. There was no such reduction recorded for the three and six months ended June 30, 2015. The Company recorded a receivable for $224,000 and $155,000 as of June 30, 2016 and December 31, 2015, respectively, to reflect the eligible costs incurred under the grant that are contractually due to the Company and such amounts are included in the prepaid expenses and other current assets on the condensed consolidated balance sheets.

7. Lease Agreement

In April 2016, the Company entered into an amendment to its facility lease agreement to increase the leased space in Milpitas, California. Under the amended lease agreement, the Company will make additional lease payments of $80,000 through April 2018.

8. Preferred Stock Warrants

In connection with the Series B redeemable convertible preferred stock financing, the Company issued warrants to purchase 4,000,000 shares of Series B redeemable convertible preferred stock at an exercise price of $0.01 per share. These warrants would become exercisable only when certain milestones were met on programs begun as a result of collaborations entered into in 2011 and 2012. In particular, 50% of the warrants would become exercisable upon the Company publicly announcing its first Investigational New Drug ("IND") candidate to the extent such IND candidate was the result of, or related to, the Company's previous collaboration(s) with Ironwood Pharmaceuticals and/or Zealand Pharma A/S, and the balance would become exercisable upon the first dosing of a human patient in a clinical trial that was the result of, or related to, the Company's previous collaboration(s) with Ironwood Pharmaceuticals and/or Zealand Pharma A/S. In August 2013, the initial closing date for the Series B financing, the Company issued 2,000,000 of the warrants ("First Tranche Warrants"). On August 15, 2014, in connection with the closing of the Series B second tranche financing, the Company issued the balance of the warrants ("Second Tranche Warrants").

The fair value of the warrants outstanding as of December 31, 2015 was remeasured at $480,000, determined using a one-step binomial lattice model in combination with the Option Pricing Model and the following assumptions: risk-free interest rate of 0.90%, expected life of 1.6 years and expected volatility of 57.0% and probability of exercisability of 95% and 0% for first tranche and second tranche, respectively.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

In March 2016, the Company made a public announcement related to a preclinical candidate which triggered the achievement of the milestone and warrants to purchase 2,000,000 shares of Series B redeemable convertible preferred stock became exercisable as of that date. In April 2016, 1,999,998 shares of Series B redeemable convertible preferred stock were issued for cash proceeds of $20,000 in connection with the exercise of warrants. Immediately prior to the exercise of the warrants, the fair value of the warrants was remeasured at $1.0 million, determined using a hybrid method of the Option Pricing Model with a 67% weighted value per share and the probability-weighted expected return method ("PWERM") with a 33% weighted value per share. The following assumptions were used in the Option Pricing Model: risk-free interest rate of 0.73%, expected life of 2.0 years and expected volatility of 52.0%. The PWERM method included probabilities of three IPO scenarios occurring in July 2016. The scenarios were weighted based on the Company's estimate of each event occurring in deriving the estimated fair value. Upon the exercise of warrants, the redeemable convertible preferred stock warrant liability of $1.0 million was reclassified to redeemable convertible preferred stock.

In May 2016, the remaining warrants for the purchase of 2,000,000 shares of Series B redeemable convertible preferred stock expired unexercised.

The Company recorded charges of zero, $525,000, $136,000 and $145,000 for the three and six months ended June 30, 2016 and 2015, respectively, representing the change in the fair value of the redeemable convertible preferred stock warrant liability in the condensed consolidated statements of operations.

9. Redeemable Convertible Preferred Stock

In April 2016, 1,999,998 shares of Series B redeemable convertible preferred stock were issued in connection with the exercise of warrants for cash proceeds of $20,000. The table below provides information on the Company's redeemable convertible preferred stock as of June 30, 2016 (in thousands, except shares and original issue price):

	Original Issue Price	Shares		Carrying Value	Aggregate Liquidation Preference
		Authorized	Issued and Outstanding		
Series A	$ 1.00	6,037,500	6,037,500	$ 1,751	$ 6,038
Series B	$ 0.50	40,000,000	37,999,998	19,850	19,000
Series C	$ 0.4979	80,337,411	80,337,411	45,009	40,000
Total redeemable convertible preferred stock		126,374,911	124,374,909	$66,610	$ 65,038

The table below provides information on the Company's redeemable convertible preferred stock as of December 31, 2015 (in thousands, except shares and original issue price):

	Original Issue Price	Shares		Carrying Value	Aggregate Liquidation Preference
		Authorized	Issued and Outstanding		
Series A	$ 1.00	6,037,500	6,037,500	$ 1,751	$ 6,038
Series B	$ 0.50	40,000,000	36,000,000	18,825	18,000
Series C	$ 0.4979	80,337,411	35,147,617	16,420	17,500
Total redeemable convertible preferred stock		126,374,911	77,185,117	$36,996	$ 41,538

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

The Company recorded $225,000 and $265,000 for the accretion of the redeemable convertible preferred stock during the three and six months ended June 30, 2016, respectively. There was no accretion recorded for the three and six months ended June 30, 2015. The accretion was recorded as an offset to the additional paid-in capital.

10. Redeemable Convertible Preferred Stock Tranche Liability

In July 2015, the Company entered into the Series C Preferred Stock Purchase Agreement ("the Series C Agreement") for the issuance of up to 80,337,411 shares of Series C redeemable convertible preferred stock at a price of $0.4979 per share, in multiple closings. The initial closing occurred on July 10, 2015, whereby 35,147,617 shares of Series C redeemable convertible preferred stock were issued for gross proceeds of approximately $17.5 million. According to the initial terms of the Series C Agreement, the Company could issue 45,189,794 additional shares under the same terms as the initial closing, in a subsequent closing ("Series C Second Tranche") contingent upon the achievement of certain development milestones.

On the date of the initial closing, the Company recorded a Series C redeemable convertible preferred stock liability of $1.0 million, as the fair value of the obligation/right to complete the Series C Second Tranche. The fair value of the Series C redeemable convertible preferred stock liability on the date of the initial closing was determined using a one-step binomial lattice model in combination with the option pricing method based on the following assumptions: 90% probability of achievement of the development milestones, stock price of $0.4979 per share, expected term of 1.0 year, and risk-free rate of 0.5%.

At December 31, 2015, the fair value of the Series C redeemable convertible preferred stock liability was remeasured and determined to be $1.6 million using a one-step binomial lattice model in combination with the option pricing model based on the following assumptions: 95% probability of achievement of the development milestones, stock price of $0.4979 per share, expected term of 0.53 year, and risk-free rate of 0.9%.

In March 2016, the Company completed the closing of the Series C Second Tranche and issued 45,189,794 shares of Series C redeemable convertible preferred stock for net cash proceeds of $22.5 million. At this time the Series C redeemable convertible preferred stock liability was remeasured at $5.8 million, determined using a hybrid method of the Option Pricing Model with a 67% weighted value per share and the PWERM with a 33% weighted value per share. The following assumptions were used in the Option Pricing Model: risk-free interest rate of 0.73%, expected life of 2.0 years and expected volatility of 52.0%. The PWERM method included probabilities of three IPO scenarios occurring in July 2016. The scenarios were weighted based on the Company's estimate of each event occurring in deriving the estimated fair value. Upon the closing of the Series C Second Tranche, the Series C redeemable convertible preferred stock liability was terminated and the balance of the liability of $5.8 million was reclassified to redeemable convertible preferred stock.

For the three and six months ended June 30, 2016, the Company recorded a charge of zero and $4.2 million, respectively, for the change in the fair value of the Series C redeemable convertible preferred stock liability in the condensed consolidated statements of operations.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

11. Common Stock

The Company had reserved shares of common stock for issuance, on an as-converted basis, as follows:

	June 30, 2016	December 31, 2015
Redeemable convertible preferred stock outstanding	8,577,571	5,323,103
Options issued and outstanding	1,309,845	833,178
Options available for future grants	109,030	147,219
Redeemable convertible preferred stock warrants	—	275,861
Total	9,996,446	6,579,361

12. Stock Option Plan

As of June 30, 2016, the Company has reserved 1,578,365 shares of common stock for issuance under the 2007 Stock Option Plan.

Activity under the Company's stock option plan is set forth below:

			Options Outstanding		
	Options Available for Grant	Options Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Balances at December 31, 2015	147,219	833,178	$ 1.33	8.56	
Additional options authorized	549,977	—			
Options granted	(588,166)	588,166	3.89		
Options exercised	—	(111,499)	1.28		
Balances at June 30, 2016	109,030	1,309,845	2.48	8.73	$ 4,728
Options exercisable – June 30, 2016		233,785	1.56	6.84	$ 1,058
Options vested and expected to vest – June 30, 2016		1,295,163	2.48	8.73	$ 4,681

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the fair value of the Company's common stock, as determined by the Company's Board of Directors, as of June 30, 2016.

During the six months ended June 30, 2016 and 2015, the estimated weighted-average grant-date fair value of common stock underlying options granted was $2.27 and $1.04 per share, respectively.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

Employee Stock Options Valuation

The fair value of employee and director stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Expected term (in years)	5.88	—	5.88 - 5.94	5.89
Expected volatility	62.5%	—	62.5% - 64.8%	59.8%
Risk-free interest rate	1.38%	—	1.27% - 1.38%	1.57%
Dividend yield	—	—	—	—

Stock Options Granted to Non-employees

Stock-based compensation related to stock options granted to non-employees is recognized as the stock options are earned. The fair value of the stock options granted is calculated at each reporting date using the Black-Scholes option-pricing model with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Expected term (in years)	6.83	—	6.83	—
Expected volatility	62.5%	—	62.5%	—
Risk-free interest rate	1.19%	—	1.19%	—
Dividend yield	—	—	—	—

During the three and six months ended June 30, 2016, the Company granted 17,894 shares, to non-employee consultants. No shares were granted to non-employee consultants during the three and six months ended June 30, 2015. The Company recorded stock-based compensation expense during the three and six months ended June 30, 2016 and 2015 of $18,000, $38,000, $4,000 and $9,000, respectively.

Stock-Based Compensation

Total stock-based compensation expense recognized for both employees and non-employee was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Research and development	$ 46	$ 8	$ 75	$ 16
General and administrative	60	13	87	24
Total stock-based compensation expense	$106	$ 21	$162	$ 40

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

As of June 30, 2016 there was $1.6 million of total unrecognized stock-based compensation costs that the Company expects to recognize over a period of approximately 3.6 years.

13. Net Loss per Share Attributable to Common Stockholders

As the Company had net losses for the three and six months ended June 30, 2016 and 2015, all potential common shares were determined to be anti-dilutive. The following table sets forth the computation of the basic and diluted net loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Numerator:				
Net loss	$ (7,098)	$ (3,219)	$ (18,845)	$ (5,916)
Accretion of redeemable convertible preferred stock	(225)	—	(265)	—
Net loss attributable to common stockholders	$ (7,323)	$ (3,219)	$ (19,110)	$ (5,916)
Denominator:				
Weighted-average shares used to compute net loss per common share, basic and diluted	383,910	233,531	335,855	231,518
Net loss per share attributable to common stockholders, basic and diluted	$ (19.07)	$ (13.78)	$ (56.90)	$ (25.55)

The following outstanding shares of potentially dilutive securities have been excluded from diluted net loss per share calculations for the three and six months ended June 30, 2016 and 2015, because their inclusion would be anti-dilutive:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Redeemable convertible preferred stock on an as-converted basis	8,577,571	2,899,134	8,577,571	2,899,134
Options to purchase common stock	1,309,841	468,546	1,309,841	468,546
Warrants to purchase redeemable convertible preferred stock on an as-converted basis	—	275,861	—	275,861
Total	9,887,412	3,643,541	9,887,412	3,643,541

14. Subsequent Events

In July 2016, the Company was awarded a Phase 1 SBIR Grant for $219,000 from the National Institute of Heart and Lung Diseases of the NIH in support of preclinical research aimed at discovering and optimizing lead molecules as novel peptide mimetics of the natural hepcidin hormone.

In July 2016, the Company's board of directors and stockholders approved the 2016 Equity Incentive Plan (the "2016 Plan"). Under the 2016 Plan, 1,200,000 shares of the Company's common stock have been initially reserved for the issuance of stock options, restricted stock units and other awards to employees, directors and consultants.

PROTAGONIST THERAPEUTICS, INC.

Notes to Unaudited Condensed Consolidated Financial Statements (Continued)

In July 2016, the Company's board of directors and stockholders approved the 2016 Employee Stock Purchase Plan (the "2016 ESPP"). Under the 2016 ESPP, 150,000 shares of the Company's common stock have been initially reserved for employee purchases of the Company's common stock.

On August 1, 2016, the Company effected a 1-for-14.5 reverse split of its common stock. Upon the effectiveness of the reverse stock split, (i) every 14.5 shares of outstanding common stock was combined into 1 share of common stock, (ii) the number of shares of common stock for which each outstanding option or warrant to purchase common stock is exercisable was proportionally decreased on a 1-for-14.5 basis, (iii) the exercise price of each outstanding option to purchase common stock was proportionately increased on a 1-for-14.5 basis, and (iv) the conversion ratio for each share of preferred stock which was convertible into the Company's common stock was proportionately reduced on a 1-for-14.5 basis. All of the outstanding common stock share numbers, warrants to purchase common stock, common stock share prices, common stock exercise prices and per share amounts have been adjusted, on a retroactive basis, to reflect this 1-for-14.5 reverse stock split for all periods presented. The par value per share, authorized number of shares of common stock, preferred stock and preferred stock warrants were not adjusted as a result of the reverse stock split.

On August 10, 2016, the Company's registration statements on Form S-1 (File Nos. 333-212476 and 333-213071) relating to the IPO became effective. The IPO closed on August 16, 2016, at which time the Company issued 7,500,000 shares of its common stock at a price of $12.00 per share. The Company received $83.7 million, net of underwriting discounts and commissions, but before deducting offering costs paid by the Company. In September 2016, the Company issued an additional 252,972 shares of common stock at a price of $12.00 per share following the underwriters' exercise of their option and received proceeds of $2.8 million, net of underwriting discounts and commissions.

ITEM 2. 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 our unaudited condensed financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with our audited financial statements and related notes thereto for the year ended December 31, 2015, included in our final prospectus filed with the Securities and Exchange Commission on August 12, 2016 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Prospectus").

Forward-Looking Statements

This discussion contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements are identified by words such as "believe," "will," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "could," "potentially" or the negative of these terms or similar expressions. You should read these statements carefully because they discuss future expectations, contain projections of future results of operations or financial condition, or state other "forward-looking" information. These statements relate to our future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in this report in Part II, Item 1A -"Risk Factors," and elsewhere in this report. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. We caution investors that our business and financial performance are subject to substantial risks and uncertainties.

Overview

We are a clinical-stage biopharmaceutical company with a proprietary technology platform focused on discovering and developing peptide-based new chemical entities (NCEs) to address significant unmet medical needs. Our primary focus is on developing first-in-class peptide drugs that specifically target biological pathways also targeted by currently marketed injectable antibody drugs. Compared to injectable antibody drugs, our oral peptides offer targeted delivery to the gastrointestinal (GI) tissue compartment, potential for improved safety due to minimal exposure in the blood, improved convenience and compliance due to oral delivery, and the opportunity for earlier introduction of targeted therapy for inflammatory bowel disease (IBD). Our initial lead product candidates, PTG-100 and PTG-200, are based on this approach, and we believe have the potential to transform the existing treatment paradigm for IBD, a GI disease consisting primarily of ulcerative colitis (UC) and Crohn's disease (CD).

PTG-100 is a potential first-in-class oral, alpha-4-beta-7 ($\alpha 4 \beta 7$) integrin-specific antagonist peptide product candidate which has now completed a Phase 1 clinical trial in normal healthy volunteers (NHVs). Integrins are T cell receptors that facilitate migration of inflammatory cells into the GI tissue. An integrin antagonist peptide is a small molecule designed to block this migration, which is a hallmark of IBD. In our Phase 1 clinical trial, we have established pharmacological proof-of-concept (POC) based on pharmacodynamic (PD) indicators. We plan to initiate a Phase 2b clinical trial in moderate-to-severe UC patients by the end of the fourth quarter of 2016.The $\alpha 4 \beta 7$ integrin is targeted by currently marketed injectable antibody drugs and the integrin pathway is considered to be one of the most specific biological mechanisms for IBD. Our second lead product candidate, PTG-200, is a potential first-in-class oral Interleukin-23 receptor (IL-23R) antagonist being developed initially for moderate-to-severe CD. Interleukin-23 is a protein produced by white blood cells that regulates inflammatory and immune functions. PTG-200 is currently in Investigational New Drug (IND) enabling studies, and we plan to initiate a Phase 1 clinical trial in 2017. Blocking of the integrin and Interleukin 23 (IL-23) pathways has led to FDA approved injectable antibody drugs for chronic inflammatory diseases, including IBD and psoriasis, respectively.

We believe PTG-100 and PTG-200 have the potential to transform the existing IBD treatment paradigm because they offer significant advantages over injectable antibody drugs. These complementary assets target different pathways, and potentially offer improved convenience and patient compliance, and improved safety and tolerability compared to currently approved injectable antibody drugs. We believe these potential advantages could allow our products to replace and expand the IBD market beyond the moderate-to-severe IBD patient population currently treated by injectable antibody drugs.

Our novel peptides have potential applicability in a wide range of therapeutic areas in addition to GI diseases. Our first product candidate beyond IBD is PTG-300, an injectable hepcidin mimetic, which is currently in pre-clinical development. PTG-300 has potential utility for the treatment of iron overload disorders, such as transfusion-dependent ß-Thalassemia, hereditary hemochromatosis (HH) and sickle cell disease (SCD), each of which may qualify for orphan designation.

We have not generated any revenue from product sales and we do not currently have any products approved for commercialization. We have never been profitable and have incurred net losses in each year since inception. Our net losses were $7.1 million and $3.2 million for the three months ended June 30, 2016 and 2015 respectively, and $18.8 million and $5.9 million for the six months ended June 30, 2016 and 2015, respectively. As of June 30, 2016, we had an accumulated deficit of $46.3 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 costs associated with our operations.

In August 2016, we completed our initial public offering ("IPO") of our common stock pursuant in which we issued 7,500,000 shares of our common stock at a price of $12.00 per share and received $83.7 million in cash, net of underwriting discounts and commissions, but before deducting offering costs paid by us. In September 2016, we issued an additional of 252,972 shares of common stock at a price of $12.00 per share following the underwriters' exercise of their option and received proceeds of $2.8 million, net of underwriting discounts and commissions.

Components of Our Results of Operations

Research and Development Expenses

Research and development expenses represent costs incurred to conduct research, such as the discovery and development of our product candidates. We recognize all research and development costs as they are incurred.

Research and development expenses consist primarily of the following:

- expenses incurred under agreements with clinical study sites that conduct research and development activities on our behalf;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- laboratory vendor expenses related to the preparation and conduct of preclinical, non-clinical, and clinical studies;
- costs related to production of clinical supplies and non-clinical materials, including fees paid to contract manufacturers;
- license fees; and
- facilities and other allocated expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

We recognize the funds from research and development grants as a reduction of research and development expense when the related research costs are incurred. In addition, we recognize the funds related to our Australian Research and Development Tax Incentives that are not subject to refund provisions as a reduction of research and development expense. The amounts are determined on a cost reimbursement basis and as the incentive is related to our research and development expenditures and is non-refundable regardless of whether any Australian tax is owed, the amounts have been recorded as a reduction of research and development expenses. These Australian Research and Development Tax Incentives are recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred, and the amount of the consideration can be reliably measured.

We allocate direct costs incurred to product candidates when they enter into clinical development. For product candidates in clinical development, we allocate research and development salaries, benefits, stock-based compensation expense and indirect costs to our product candidates on a program-specific basis, and we include these costs in the program-specific expenses. Program-specific expenses are unallocated when the current clinical expenses are incurred for our early stage research and drug discovery projects, our internal resources, employees and infrastructure are not tied to any one research or drug discovery project and are typically deployed across multiple projects. As such, we do not maintain information regarding these costs incurred for the early stage research and drug discovery programs on a project-specific basis prior to the clinical development stage.

The following table shows our research and development expenses incurred during the respective periods:

	Three Months Ended June 30		Six Months Ended June 30,	
	2016	2015	2016	2015
	(In thousands)			
Clinical development expense – PTG 100	$ 3,858	$ —	$ 7,874	$ —
Discovery research expense	2,336	2,407	4,524	4,690
Less: Reimbursement of expenses under grants and incentives	(498)	(110)	(1,077)	(210)
Total research and development expenses	$ 5,696	$ 2,297	$11,321	$4,480

We expect our research and development expenses will increase as we progress our product candidates, advance our discovery research projects into the pre-clinical stage and continue our early stage research. The process of conducting research, identifying potential product candidates and conducting pre-clinical and clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for our product candidates. The probability of success of the product candidates may be affected by numerous factors, including pre-clinical data, clinical data, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

General and Administrative Expenses

General and administrative expenses consist 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. Allocated expenses consist of expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies. We expect to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the Securities and Exchange Commission, and those of the national securities exchange on which our securities are traded, additional insurance expenses, investor relations activities and other administrative and professional services.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and available-for-sale securities.

Change in Fair Value of Redeemable Convertible Preferred Stock Tranche and Warrant Liabilities

Change in fair value of redeemable convertible preferred stock tranche and warrant liabilities consists of the remeasurement of the fair value of financial liabilities related to our obligation to sell additional redeemable convertible preferred stock shares in subsequent closings contingent upon the achievement of certain development milestones or approval of investors and warrants for the purchase of redeemable convertible preferred stock.

In connection with our Series C redeemable convertible preferred stock financing we were obligated to sell additional shares of Series C redeemable convertible preferred stock in a subsequent closing contingent upon the achievement of certain development milestones or upon the approval of the investors. We recorded this redeemable convertible preferred stock tranche liability incurred as a derivative financial instrument liability at the fair value on the date of issuance, and we remeasure the liability on each subsequent balance sheet date. In March 2016, upon closing of the second tranche of the Series C redeemable convertible preferred stock, the fair value of the tranche liability was remeasured and the liability was reclassified to redeemable convertible preferred stock.

In addition, in connection with the issuance of our Series B redeemable convertible preferred stock financing, we issued freestanding warrants to purchase shares of Series B redeemable convertible preferred stock. We account for these warrants as a liability in our consolidated financial statements because the underlying instrument into which the warrants are exercisable contains redemption provisions that are outside our control. Upon the exercise of warrants in April 2016, the fair value of the redeemable convertible preferred stock warrant liability was remeasured and the liability was reclassified to redeemable convertible preferred stock. The remaining warrants expired unexercised in May 2016 and accordingly, are no longer subject to remeasurement.

Critical Accounting Polices and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these consolidated 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 consolidated financial statements, as well as the reported revenue generated and 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.

There have been no material changes in our critical accounting policies during the six months ended June 30, 2016, as compared to those disclosed in the *"Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates"* in our prospectus filed with the SEC on August 12, 2016 pursuant to Rule 424(b) under the Securities Act.

Results of Operations

Comparison of the Three Months Ended June 30, 2016 and 2015

	Three Months Ended June 30,			
	2016	2015	Dollar Change	% Change
	(Dollars in thousands)			
Operating expenses:				
Research and development	$ 5,696	$ 2,297	$ 3,399	148
General and administrative	1,395	786	609	77
Total operating expenses	7,091	3,083	4,008	130
Loss from operations	(7,091)	(3,083)	(4,008)	130
Interest income	27	—	27	*
Change in fair value of redeemable convertible preferred stock tranche and warrant liabilities	—	(136)	136	100
Other expense	(34)	—	(34)	*
Net loss	$(7,098)	$(3,219)	$(3,879)	121

* Percentage not meaningful

Research and Development Expenses

Research and development expenses increased $3.4 million, or 148%, from $2.3 million for the three months ended June 30, 2015 to $5.7 million for the three months ended June 30, 2016. The increase was primarily due to an increase of $1.2 million related to increased contract manufacturing activities for PTG-100 clinical trials and other product candidate studies, an increase of $0.8 million in PTG-100 Phase 1 clinical trials and other related studies, an increase of $0.8 million in pre-clinical activities for our product candidates, an increase of $0.6 million in salaries and employee-related expenses due to an increase in headcount, an increase of $0.3 million in costs to third party consultants and an increase of $0.1 million in facility expenses. The increases were partially offset by an increase of $0.4 million in government grants recognized as a reduction of research and development expenses, primarily due to the increase in our Australian Research and Development Tax Incentive grant.

General and Administrative Expenses

General and administrative expenses increased $0.6 million, or 77%, from $0.8 million for the three months ended June 30, 2015, to $1.4 million for the three months ended June 30, 2016. The increase was primarily due to an increase of $0.5 million in professional service fees and an increase of $0.1 million in salaries and employee-related expenses due to an increase in headcount to support the growth of our operations.

Change in Fair Value of Redeemable Convertible Preferred Stock Tranche and Warrant Liabilities

The change in estimated fair value associated with redeemable convertible preferred stock tranche liability and warrant liability decreased $0.1 million, from a charge of $0.1 million for the three months ended June 30, 2015 to zero for the three months ended June 30, 2016 due to the settlement of Series C redeemable convertible preferred stock tranche liability in March 2016 and the exercise of the convertible preferred stock warrants in April 2016.

Comparison of the Six Months Ended June 30, 2016 and 2015

	Six Months Ended June 30,			
	2016	2015	Dollar Change	% Change
	(Dollars in thousands)			
Operating expenses:				
Research and development	$ 11,321	$ 4,480	$ 6,841	153
General and administrative	2,810	1,292	1,518	117
Total operating expenses	14,131	5,772	8,359	145
Loss from operations	(14,131)	(5,772)	(8,359)	145
Interest income	39	1	38	*
Change in fair value of redeemable convertible preferred stock tranche and warrant liabilities	(4,719)	(145)	(4,574)	*
Other expense	(34)	—	(34)	*
Net loss	$(18,845)	$(5,916)	$(12,929)	219

* Percentage not meaningful

Research and Development Expenses

Research and development expenses increased $6.8 million, or 153%, from $4.5 million for the six months ended June 30, 2015 to $11.3 million for the six months ended June 30, 2016. The increase was primarily due to an increase of $2.4 million related to increased contract manufacturing activities for PTG-100 clinical trials and other product candidate studies, an increase of $1.7 million in PTG-100 Phase 1 clinical trials and other related studies, an increase of $1.6 million in pre-clinical activities for our product candidates, an increase of $0.9 million in salaries and employee-related expenses due to an increase in headcount, an increase of $0.6 million in costs to third party consultants, an increase of $0.3 million due to achieving certain development milestones in a prior collaboration agreement related to the initiation of preclinical development studies on PTG-300, and an increase of $0.2 million in facility expenses. The increases were partially offset by an increase of $0.9 million in government grants recognized as a reduction of research and development expenses, primarily due to the increase in our Australian Research and Development Tax Incentive grant and funds earned under the Small Business Innovation Research grant award obtained in 2015.

General and Administrative Expenses

General and administrative expenses increased $1.5 million, or 117%, from $1.3 million for the six months ended June 30, 2015, to $2.8 million for the six months ended June 30, 2016. The increase was primarily due to an increase of $1.2 million in professional service fees and an increase of $0.2 million in salaries and employee-related expenses due to an increase in headcount to support the growth of our operations.

Change in Fair Value of Redeemable Convertible Preferred Stock Tranche and Warrant Liabilities

The change in estimated fair value associated with redeemable convertible preferred stock tranche liability and warrant liability increased $4.6 million, from a charge of $0.1 million for the six months ended June 30, 2015 to $4.7 million for the six months ended June 30, 2016, was due to the fair value remeasurement of the outstanding mark to market liabilities.

Liquidity and Capital Resources

Liquidity and Capital Expenditures

As of June 30, 2016, we had $20.2 million of cash, cash equivalents and available-for-sale securities and an accumulated deficit of $46.3 million. In August 2016, we completed the IPO and received proceeds of $83.7 million, net of underwriting discounts and commissions, but before deducting offering costs paid by us. In September 2016, we issued an additional of 252,972 shares of common stock at a price of $12.00 per share following the underwriters' exercise of their option and received proceeds of $2.8 million, net of underwriting discounts and commissions.

Our primary uses of cash are to fund operating expenses, primarily research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable and accrued expenses.

We believe, based on our current operating plan and expected expenditures, that our existing cash, cash equivalents, available-for-sale securities and the net proceeds from our IPO in August 2016, will be sufficient to meet our anticipated operating and capital expenditure requirements for at least the next 18 months. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Specifically, we expect to incur substantial expenses in connection with our planned Phase 2b clinical trial for PTG-100, our IND-enabling studies and planned clinical trial for PTG-200 and IND enabling studies for PTG-300 and any other clinical trials that we may conduct. Furthermore, if our planned preclinical and clinical trials are successful, or our other product candidates enter clinical trials or advance beyond the discovery stage, we will need to raise additional capital in order to further advance our product candidates towards regulatory approval. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. We anticipate that we will need to raise substantial additional capital, the requirements of which will depend on many factors, including:

- the progress, timing, scope, results and costs of our preclinical studies and clinical trials for our product candidates, including the ability to enroll patients in a timely manner for our clinical trials;
- the costs of obtaining clinical and commercial supplies and any other product candidates we may identify and develop;
- our ability to successfully commercialize the product candidates we may identify and develop;
- the manufacturing, selling and marketing costs associated with our lead product candidates and any other product candidates we may identify and develop, including the cost and timing of expanding our sales and marketing capabilities;
- the amount and timing of sales and other revenues from our lead product candidates and any other product candidates we may identify and develop, including the sales price and the availability of adequate third-party reimbursement;
- the cash requirements of any future acquisitions or discovery of product candidates;
- the time and cost necessary to respond to technological and market developments;
- the extent to which we may acquire or in-license other product candidates and technologies;
- our ability to attract, hire and retain qualified personnel; and
- the costs of maintaining, expanding and protecting our intellectual property portfolio.

Adequate additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies. Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

The following table summarizes our cash flows for the periods indicated:

	Six Month Ended June 30,	
	2016	2015
	(In thousands)	
Cash used in operating activities	$(13,312)	$(5,877)
Cash provided by (used in) investing activities	$ 1,113	$ (66)
Cash provided by financing activities	$ 21,881	$ 57

Cash Flows from Operating Activities

Cash used in operating activities for the six months ended June 30, 2016 was $13.3 million, consisting of a net loss of $18.8 million, which was offset by non-cash charges of $5.1 million and a net change of $0.4 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of $4.2 million for the change in fair value of redeemable convertible preferred stock tranche liability, $0.5 million for the change in fair value of convertible preferred stock warrant liability, $0.2 million for depreciation and amortization expense and $0.2 million for stock-based compensation. The increase in our net operating assets and liabilities was due primarily to a decrease of $1.1 million in prepaid and other current assets related to expensing of costs for research activities that occurred during the current period and an increase of $0.3 million in our accounts payable and accrued liabilities related to an increase in research and development activities, offset by a $1.0 million increase in the receivable related to the Australian Research and Development Tax Incentives.

Cash used in operating activities for the six months ended June 30, 2015 was $5.9 million, consisting of a net loss of $5.9 million, which was offset by non-cash charges of $0.3 million and a net change of $0.3 million in our net operating assets and liabilities. The non-cash charges were primarily comprised of $0.1 million for the change in fair value of convertible preferred stock warrant liability and $0.1 million for depreciation and amortization expense. The decrease in our net operating assets and liabilities was due primarily to an increase of $0.2 million in the receivable related to the Australian Research and Development Tax Incentives.

Cash Flows from Investing Activities

Cash provided by investing activities for the six months ended June 30, 2016 was $1.1 million, consisting of the proceeds from maturities of our available-for-sale securities of $7.8 million, which were partially offset by our purchase of available-for-sale securities of $6.4 million and our purchase of property and equipment of $0.3 million. The purchase of property and equipment was primarily related to the expansion of our laboratory and related equipment.

Cash used in investing activities for the six months ended June 30, 2015 was related to our purchase of property and equipment of $66,000.

Cash Flows from Financing Activities

Cash provided by financing activities for the six months ended June 30, 2016 was $21.9 million, consisting of net proceeds of $22.5 million from the issuance of redeemable convertible preferred stock and proceeds of $0.1 million from the issuance of common stock upon exercise of stock options, which were partially offset by our payments of deferred initial public offering costs of $0.8 million.

Cash provided by financing activities for the six months ended June 30, 2015 was $57,000, consisting of proceeds from the issuance of common stock upon exercise of stock options.

Contractual Obligations and Other Commitments

During the six months ended June 30, 2016, there were no material changes to our contractual obligations and commitments described under *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our prospectus filed on August 12, 2016 with the SEC pursuant to Rule 424(b) under the Securities Act.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not have any off-balance sheet arrangements, as defined under SEC rules, including the use of structured finance, special purpose entities or variable interest entities.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities.

We had $20.2 million and $11.9 million in cash, cash equivalents and available-for-sale securities as of June 30, 2016 and December 31, 2015, respectively. Cash and cash equivalents consist of cash, money market funds and corporate bonds. Available-for-sale securities consist of corporate bonds and commercial paper. Such interest earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant. We had no outstanding debt as of June 30, 2016.

Approximately $0.4 million and $0.6 million of our cash balance was located in Australia as of June 30, 2016 and December 31, 2015, respectively. Our expenses, except those related to our Australian operations, are generally denominated in U.S. dollars. For our operations in Australia, the majority of the expenses are denominated in Australian dollars. To date, we have not had a formal hedging program with respect to foreign currency, but we may do so in the future if our exposure to foreign currency should become more significant. A 10% increase or decrease in current exchange rates would not have a material effect on our consolidated financial results.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of disclosure controls and procedures

As required by Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this quarterly report. Based on the evaluation of our disclosure controls and procedures, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this quarterly report, our disclosure controls and procedures were not effective at the reasonable assurance level as a result of the material weakness described below.

Material Weakness

In connection with the audit of our consolidated financial statements for the years ended December 31, 2014 and 2015, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting. 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 our annual or interim financial statements will not be prevented or detected on a timely basis.

The first material weakness related to a deficiency in the operation of our internal controls over the accounting for non-routine, complex equity transactions, which resulted in material post-closing adjustments to the convertible preferred stock, additional paid-in capital, interest expense, and gain from modification of the redeemable convertible preferred stock balances in the consolidated financial statements for the year ended December 31, 2013. Our lack of adequate accounting personnel has resulted in the identification of a second material weakness in our internal control over financial reporting for the years ended December 31, 2014 and 2015. Specifically, we did not, and have not historically, appropriately designed and implemented controls over the review and approval of manual journal entries and the related supporting journal entry calculations.

We are in the early phases of the implementation of our remediation plan. We have taken certain actions to remediate this material weakness, including adding additional accounting personnel for review of account reconciliations and manual journal entries. We intend to hire additional finance and accounting personnel, utilize consultants with technical accounting expertise when needed, design and implement segregation of duties procedures and establish formal written policies for our accounting function by the end of 2016.

Changes in internal control over financial reporting

Other than the aforementioned remediation efforts, there have been no changes in our internal control over financial reporting that occurred during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Internal control over financial reporting may not prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Also, projections of any evaluation of effectiveness of internal control to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From time to time, we may become subject to litigation and claims arising in the ordinary course of business. We are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results or financial condition.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with the other information included or incorporated by reference 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 consolidated financial statements and the related notes. We cannot assure you that any of the events discussed in the risk factors below will not occur. The occurrence of any of the events or developments described below could have a material and adverse impact on our business, results of operations, financial condition, and cash flows and future prospects and, if so, our future prospects would likely be materially and adversely affected. If any of such events were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. Although we have discussed all known material risks, the risks described below are not the only ones that we may face, and additional risks or uncertainties not known to us or that we currently deem immaterial may also impair our business and future prospects. The risks relating to our business set forth in our prospectus dated August 10, 2016 that forms a part of the Company's Registration Statement on Form S-1, filed with the SEC, are set forth below and are unchanged substantively as of June 30, 2016, except for those risks designated by an asterisk (*).

Risks Related to Our Financial Position and Capital Requirements

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future. We have never generated any revenue from product sales and may never be profitable.*

We have incurred significant operating losses since our inception in 2006. Our net loss for the years ended December 31, 2014 and 2015 was approximately $11.1 million and $14.9 million, respectively, and $18.8 million for the six months ended June 30, 2016. As of June 30, 2016, we had an accumulated deficit of $46.3 million. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect to continue incurring significant research, development and other expenses related to our ongoing operations and product development, and as a result, we expect to continue incurring losses for the foreseeable future. We also expect these losses to increase as we continue our development of, and seek regulatory approvals for, our peptide-based product candidates.

We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we do not currently have any product candidates in registration or pivotal clinical trials. If any of our peptide-based product candidates fail in clinical trials or do not gain regulatory approval, or even if approved, fail to achieve market acceptance, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

If one or more of our peptide-based product candidates is approved for commercial sale and we retain commercial rights, we anticipate incurring significant costs associated with manufacturing and commercializing such approved peptide-based product candidate. Therefore, even if we are able to generate revenue from the sale of any approved product, we may never become profitable.

We are an early clinical-stage biopharmaceutical company with no approved products and no historical product revenue, which makes it difficult to assess our future prospects and financial results.

We are an early clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of uncertainty. Our operations to date have been limited to developing our technology, undertaking pre-clinical studies and clinical trials of our pipeline candidates, including pre-clinical studies and clinical trial of PTG-100 and pre-clinical studies of PTG-200 and PTG-300, as well as our proprietary technology platform. We have successfully filed a CTN in Australia to support the Phase 1 clinical trial of PTG-100. To date, we have not filed a U.S. Investigational New Drug (IND) application for any of our product candidates and have only commenced human clinical trials in PTG-100. As an early clinical-stage company, we have not yet demonstrated an ability to generate revenue or successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields such as biopharmaceutical drug discovery and development. Consequently, the ability to accurately assess our future operating results or business prospects is significantly more limited than if we had a longer operating history or approved products on the market.

We expect that our financial condition and operating results will fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control, including, but not limited to:

- the clinical outcomes from the continued development of our product candidates;
- potential side effects of our product candidates that could delay or prevent approval or cause an approved drug to be taken off the market;
- our ability to obtain, as well as the timeliness of obtaining, additional funding to develop, and potentially manufacture and commercialize our product candidates;
- competition from existing products directed against the same biological target or therapeutic indications of our product candidates as well as new products that may receive marketing approval;
- the entry of generic versions of products that compete with our product candidates;
- the timing of regulatory review and approval of our product candidates;
- market acceptance of our product candidates that receive regulatory approval, if any;
- our ability to establish an effective sales and marketing infrastructure directly or through collaborations with third parties;
- the ability of patients or healthcare providers to obtain coverage or sufficient reimbursement for our products;
- whether Johnson & Johnson Development Corporation (JJDC) decides to exercise its rights of first negotiation on any of our assets that are subject to the Letter Agreement with JJDC, including PTG-200, and we have to negotiate with JJDC for prolonged periods pursuant to the aforementioned agreement;
- the ability of third party manufacturers to manufacture in accordance with current good manufacturing practices (GMP) our product candidates for the conduct of clinical trials and, if approved, for successful commercialization;
- our ability as well as the ability of any third party collaborators, to obtain, maintain and protect intellectual property rights covering our product candidates and technologies, and our ability to develop, manufacture and commercialize our product candidates without infringing on the intellectual property rights of others;
- our ability to add infrastructure and manage adequately our future growth; and
- our ability to attract and retain key personnel with appropriate expertise and experience to manage our business effectively.

Accordingly, the likelihood of our success must be evaluated in light of many potential challenges and variables associated with an early-stage biopharmaceutical company, many of which are outside of our control, and past results, including operating or financial results, should not be relied on as an indication of future results.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all.*

Our operations have consumed substantial amounts of cash since inception. We conducted a Phase 1 clinical trial of PTG-100 in healthy volunteers and we are preparing to conduct a Phase 2b clinical trial of PTG-100 in patients with moderate-to-severe ulcerative colitis (UC), and we have also commenced IND-enabling studies of PTG-200 and PTG-300. Developing pharmaceutical product candidates, including conducting pre-clinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and, if we are successful, to commercialize any of our current product candidates. If the U.S. Food and Drug Administration (FDA) or any foreign regulatory agency, such as the European Medicines Agency (EMA), requires that we perform studies or trials in addition to those that we currently anticipate with respect to the development of PTG-100, PTG-200 or any of our other product candidates, or repeat studies or trials, our expenses would further increase beyond what we currently expect, and any delay resulting from such further or repeat studies or trials could also result in the need for additional financing.

Based upon our current operating plan and expected expenditures, we believe that our existing cash, cash equivalents, and available-for-sale securities, including the proceeds of the IPO, will be sufficient to fund our operations for at least the next 18 months. This period could be shortened if there are any significant increases beyond our expectations in spending on development programs or more rapid progress of development programs than anticipated. Our existing capital resources, including the net proceeds from the IPO, will not be sufficient to enable us to initiate any pivotal clinical trials. Accordingly, we expect that we will need to raise substantial additional funds in the future in order to complete clinical development or commercialize any of our product candidates. Our funding requirements and the timing of our need for additional capital are subject to change based on a number of factors, including:

- the rate of progress and the cost of our studies of PTG-100, PTG-200, and PTG-300 and any other product candidates;
- the number of product candidates that we intend to develop using our technology platform;
- the costs of research and pre-clinical studies to support the advancement of other product candidates into clinical development;
- the timing of, and costs involved in, seeking and obtaining approvals from the FDA and comparable foreign regulatory authorities, including the potential by the FDA or comparable regulatory authorities to require that we perform more studies than those that we currently expect;
- the costs of preparing to manufacture PTG-100 or PTG-200 on a scale sufficient to enable large-scale clinical trials and commercial supply;
- the timing and cost of transitioning our product formulations into the formulations we intend to use in registration trials and commercialize;
- the costs of commercialization activities if PTG-100 or PTG-200 or any future product candidate is approved, including the formation of a sales force;
- the degree and rate of market acceptance of any products launched by us or our partners;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- our need and ability to hire and retain additional personnel;
- our ability to enter into additional collaboration, licensing, commercialization or other arrangements and the terms and timing of such arrangements; and
- the emergence of competing technologies or other adverse market developments.

If we are unable to obtain additional funding from equity offerings or debt financings, including on a timely basis, we may be required to:

- seek collaborators for one or more of our peptide-based product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms our rights to technologies or peptide-based product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail one or more of our research or development programs or cease operations altogether.

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

We may seek additional funding through a combination of equity offerings, debt financings, collaborations and/or licensing arrangements. Additional funding may not be available to us on acceptable terms, or at all. 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. The incurrence of indebtedness and/or the issuance of certain equity securities could result in fixed payment obligations and could also result in certain additional restrictive covenants, such as limitations on our ability to incur debt and/or issue additional equity, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. In the event that we enter into collaborations and/or licensing arrangements in order to raise capital, we may be required to accept unfavorable terms, including relinquishing or licensing to a third party on unfavorable terms our rights to our proprietary technology platform or peptide-based product candidates that we otherwise would seek to develop or commercialize ourselves or potentially reserve for future potential arrangements when we might be able to achieve more favorable terms.

Risks Related to Our Business and Industry

***We are heavily dependent on the success of our lead product candidates, PTG-100, which is in early-stage clinical development, and PTG-200, which is in pre-clinical development, and the development of other product candidates such as PTG-300, and if any of these products fail to receive regulatory approval or are not successfully commercialized, our business would be adversely affected. **

We currently have no product candidates that are in registration or pivotal clinical trials or are approved for commercial sale, and we may never be able to develop a marketable product. We expect that a substantial portion of our efforts and expenditures over the next few years will be devoted to our lead product candidates, PTG-100 and PTG-200 targeting inflammatory bowel disease (IBD), and the development of other product candidates such as PTG-300 which targets iron overload disorders. We cannot be certain that PTG-100, PTG-200, PTG-300 or any other product candidates will receive regulatory approval or, if approved, be successfully commercialized. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of PTG-100, PTG-200, and PTG-300 will remain subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, each of which has differing regulations. In addition, even if approved, our pricing and reimbursement will be subject to further review and discussions with payors. We are not permitted to market any product candidate in the United States until after approval of a new drug application (NDA) from the FDA, or in any foreign countries until after approval of a marketing application by corresponding regulatory authorities. We completed a Phase 1 clinical trial for PTG-100 in June 2016. We will need to conduct larger, more extensive clinical trials in the target patient population to support a potential application for regulatory approval by the FDA or corresponding regulatory authorities, and we do not expect to be in a position to do so for the near term. We will not receive any preferential or expedited review of any application for regulatory approval by virtue of the fact that our product candidates target biological pathways that are also targeted by currently marketed injectable antibody drugs, and our product candidates will be subject to the regulatory review processes applicable to completely new drugs.

We have not previously submitted an NDA to the FDA, or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trial or receive regulatory approval. Filing an application and obtaining regulatory approval for a pharmaceutical product candidate is an extensive, lengthy, expensive and inherently uncertain process, and the regulatory authorities may delay, limit or deny approval of our product candidates for many reasons, including:

- we may not be able to demonstrate that any of our product candidates is safe and effective to the satisfaction of the FDA or comparable foreign regulatory authorities;
- the FDA or comparable foreign regulatory authorities may require additional pre-clinical studies or clinical trials prior to granting approval, which would increase our costs and extend the pre-approval development process;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA may disagree with the number, design, size, conduct or statistical analysis of one or more of our clinical trials;
- contract research organizations (CROs) that we retain to conduct clinical trials may take actions outside of our control that materially and adversely impact our clinical trials;
- the FDA or comparable foreign regulatory authorities may disagree with, or not accept, our interpretation of data from our pre-clinical studies and clinical trials;
- the FDA may require development of a costly and extensive risk evaluation and mitigation strategy (REMS), as a condition of approval;
- the FDA may identify deficiencies in our manufacturing processes or facilities or those of our third-party manufacturers which would be required to be corrected prior to regulatory approval;
- the success or further approval of competitor products approved in indications in which we undertake development of our product candidates may change the standard of care or change the standard for approval of our product candidate in our proposed indications;
- the FDA or comparable foreign regulatory authorities may change their approval policies or adopt new regulations; and
- relative bioavailability data in monkeys or humans from the formulation bridging component of our Phase 1 trial may not support introduction of the capsule formulation into the Phase 2b clinical trial of PTG-100 or the FDA may find the data inadequate and request another trial.

Our peptide-based product candidates will require additional research, clinical development, manufacturing activities, regulatory approval in multiple jurisdictions (if regulatory approval can be obtained at all), securing sources of commercial manufacturing supply and building of or partnering with a commercial organization. We cannot assure you that our clinical trials for PTG-100 or our planned clinical trials for PTG-200 will be initiated or completed in a timely manner or successfully, or at all. Further we cannot be certain that we plan to advance any other peptide-based product candidates into clinical trials. Moreover, any delay or setback in the development of any product candidate, in particular PTG-100, PTG-200, or PTG-300, would be expected to adversely affect our business and cause our stock price to fall.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

Our business and future profitability is substantially dependent on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize our most advanced peptide-based product candidates, PTG-100, which has completed a Phase 1 clinical trial for UC, and PTG-200 and PTG-300, which are in pre-clinical development. We have not yet filed an IND for any of our product candidates. We are not permitted to market or promote any of our peptide-based product candidates before we receive regulatory approval from the FDA, the EMA or any other foreign regulatory authority, and we may never receive such regulatory approval for any of our peptide-based product candidates. The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. Approval policies, regulations and the types and amount of clinical and manufacturing data necessary to gain approval may change during the course of 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 product candidates we have in development or may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may fail to achieve the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data submitted in support of regulatory approval;
- the data collected from pre-clinical studies and clinical trials of our peptide-based product candidates may not be sufficient to support the submission of an NDA, supplemental NDA, Biologics License Application (BLA) or other regulatory submissions necessary to obtain regulatory approval in the United States or elsewhere;
- we or our contractors may not meet the GMP and other applicable requirements for manufacturing processes, procedures, documentation and facilities necessary for approval by the FDA or comparable foreign regulatory authorities; and
- changes to the approval policies or regulations of the FDA or comparable foreign regulatory authorities with respect to our product candidates may result in our clinical data becoming insufficient for approval.

The lengthy regulatory approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market PTG-100 and PTG-200, our lead product candidates, or any other product candidate, such as PTG-300, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain regulatory approval, regulatory authorities may approve our product candidates for fewer or more limited indications than what we requested approval for, may include safety warnings or other restrictions that may negatively impact the commercial viability of our product candidates, including the potential for a favorable price or reimbursement at a level that we would otherwise intend to charge for our products. Likewise, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials or the conduct of an expensive REMS, which could significantly reduce the potential for commercial success or viability of our product candidates. Any of the foregoing possibilities could materially harm the prospects for our product candidates and business and operations.

We have not previously submitted an NDA, a BLA, a Marketing Authorization Application (MAA), or any corresponding drug approval filing to the FDA, the EMA or any comparable foreign authority for any peptide-based product candidate. Further, our product candidates may not receive regulatory approval even if we complete such filings. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development. Further, we have never conducted a Phase 2 or Phase 3 clinical trial or submitted an NDA.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. The results of pre-clinical studies and early clinical trials of our product candidates and studies and trials of other products may not be predictive of the results of later-stage clinical trials. In addition to our planned pre-clinical studies and clinical trials, we expect to have to complete at least two large scale, or adequate, well-controlled trials to demonstrate substantial evidence of efficacy and safety for each product candidate we intend to commercialize. Further, given the patient populations for which we are developing therapeutics, we expect to have to evaluate long-term exposure to establish the safety of our therapeutics in a chronic dose setting. We have never conducted a Phase 2 or Phase 3 clinical trial or submitted an NDA, and as a result, we have no history or track-record to rely on when entering these phases of the development cycle. For example, the results generated to date in pre-clinical studies and the Phase 1 clinical trial for PTG-100 do not ensure that future Phase 2 clinical trials or later clinical trials will have similar results or be successful. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. Clinical trial failures may result from a multitude of factors including, but not limited to, flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety and/or efficacy traits of the product candidate. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or pre-clinical studies.

We may experience delays in ongoing clinical trials, and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- obtaining regulatory approvals to commence a clinical trial;
- reaching agreement on acceptable terms with prospective 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;
- fraud or negligence on the part of CROs, contract manufacturing organizations (CMOs), consultants or contractors;
- obtaining institutional review board (IRB) or ethics committee (EC), approval at each site;
- recruiting suitable patients to participate in a clinical trial;
- having patients complete a clinical trial or return for post-treatment follow-up;
- clinical sites deviating from the clinical trial's protocol or dropping out of a clinical trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of product candidate for use in clinical trials.

We could encounter delays if a clinical trial is modified, suspended or terminated by us, by the IRBs or ECs of the institutions in which such clinical trials are being conducted, by a Data Safety Monitoring Board, for such trial or by the FDA or other regulatory authorities. Such authorities may impose a modification, suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical trial protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, 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 revenue 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 revenue. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval.

Enrollment and retention of patients in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control.

We may encounter delays in enrolling, be unable to enroll or maintain, a sufficient number of patients to complete any of our clinical trials. Patient enrollment and retention in clinical trials is a significant factor in the timing of clinical trials and depends on many factors, including the size and nature of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical trials of competing drugs for the same indication, the proximity of patients to clinical trial sites and the eligibility criteria for the clinical trial. Furthermore, any negative results we may report in clinical trials of our product candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same candidate. For example, we are aware of a number of therapies that are commercialized or are being developed for IBD and we expect to face competition from these investigational drugs or approved drugs for potential subjects in our clinical trials, which may delay the pace of enrollment in our planned clinical trials. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible.

All of our peptide-based product candidates other than PTG-100 are in research or pre-clinical development and have not entered into clinical trials. If we are unable to develop, test and commercialize our peptide-based product candidates, our business will be adversely affected.

As part of our strategy, we also seek to discover, develop and commercialize a portfolio of new peptide-based product candidates in addition to PTG-100. Research programs to identify appropriate biological targets pathways and product candidates require substantial scientific, technical, financial and human resources, whether or not any product candidates are ultimately identified. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including:

- our financial and internal resources are insufficient;
- our research methodology used may not be successful in identifying potential product candidates;
- competitors may develop alternatives that render our product candidates uncompetitive;
- our other product candidates may be shown to have harmful side effects or other characteristics that indicate such product candidate is unlikely to be effective or otherwise unlikely to achieve applicable regulatory approval;
- our product candidates may not be capable of being produced in commercial quantities at an acceptable cost, or at all; or
- a product candidate may not be accepted by patients, the medical community, healthcare providers or third-party payors.

Our research and development strategy for our lead product candidates relies in large part on clinical data and results obtained from antibody and small molecule products that are approved or in late-stage development that could ultimately prove to be inaccurate or unreliable for use with our peptide-based product candidate approach.

As part of our strategy to mitigate clinical development risk, we seek to develop peptide-based product candidates against biological targets and pathways which have been identified as addressable by approved or later stage products in development. While we utilize pre-clinical *in vivo* and *in vitro* models as well as clinical biomarkers to assess potential safety and efficacy early in the candidate selection and development process, this strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable or otherwise not applicable to the indications in which we develop our peptide-based product candidates. We will have to conduct clinical trials to show the safety and efficacy of our peptide-based product candidates against the identified biological targets and pathways to show that our peptide-based product candidates can address the identified mechanism of action shown by these third party results. For example, PTG-100 is an α4ß7 integrin antagonist that targets the same target as the currently marketed injectable antibody drug, Entyvio®, and PTG-200 targets the IL-23 biological pathway, which is a pathway targeted by the currently marketed injectable antibody drug, Stelara®, approved in a different indication and which has demonstrated positive results in a Phase 3 clinical trial in IBD. If our interpretation of the third party clinical data and results from molecules directed against the same biological target or pathway or our pre-clinical *in vivo* and *in vitro* models prove inaccurate or our assumptions and conclusions about the applicability of our peptide-based product candidates against the same biological targets or pathways are incorrect or inaccurate, then our development efforts may prove longer and more extensive and our research and development strategy and business and operations could be significantly harmed.

Our proprietary peptide platform may not result in any products of commercial value.

We have developed a proprietary peptide technology platform to enable the identification, testing, design and development of new product candidates. We cannot assure you that our peptide platform will work, nor that any of these potential targets or other aspects of our proprietary drug discovery and design platform will yield product candidates that could enter clinical development and, ultimately, be commercially valuable. Although we expect to continue to enhance the capabilities of our proprietary platform by developing and integrating existing and new research technologies, we may not be successful in any of our enhancement and development efforts. For example, we may not be able to enter into agreements on suitable terms to obtain technologies required to develop certain capabilities of our peptide platform. In addition, we may not be successful in developing the conditions necessary to simulate specific tissue function from multiple species, or otherwise develop assays or cell cultures necessary to expand these capabilities. If our enhancement or development efforts are unsuccessful, we may not be able to advance our drug discovery capabilities as quickly as we expect or identify as many potential drug candidates as we desire.

Our product candidates may cause undesirable side effects or have other properties impacting safety that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in limiting the commercial opportunity for our product candidates if approved.

Undesirable side effects that may be caused by our product candidates or caused by similar approved drugs or product candidates in development by other companies, 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 authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or adverse events related to our product candidates. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of our product candidates for any or all targeted indications. In addition, drug-related side effects could negatively affect patient recruitment or the ability of enrolled patients to complete the trial and even if our clinical trials are completed and our product candidate is approved, drug-related side effects could restrict the label or result in potential product liability claims. Any of these occurrences could significantly harm our business, financial condition and prospects significantly.

Moreover, since our product candidates PTG-100 and PTG-200 are being developed for indications for which injectable antibody drugs have been approved, we expect that our clinical trials would need to show a risk/benefit profile that is competitive with those existing products and product candidates in order to obtain regulatory approval or, if approved, a product label that is favorable for commercialization.

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

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular peptide-based product candidate which could significantly harm our business and prospects.

We rely on third parties to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or do not meet regulatory requirements or expected deadlines, we may not be able to obtain timely regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third party CROs to monitor and manage clinical trials and collect data for our pre-clinical studies and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that their conduct meets regulatory requirements and that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs does not relieve us of our regulatory responsibilities. Thus, we and our CROs are required to comply with good clinical practices (GCPs), which are regulations and guidelines promulgated by the FDA, the EMA and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may not accept the data or require us to perform additional clinical trials before considering our filing for regulatory approval or approving our marketing application. We cannot assure you that upon inspection by a regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCPs. While we have agreements governing activities of our CROs, we may have limited influence over their actual performance and the qualifications of their personnel conducting work on our behalf. In addition, significant portions of the clinical studies for our peptide-based product candidates are expected to be conducted outside of the US, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCPs. Failure to comply with applicable regulations in the conduct of the clinical studies for our peptide-based product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

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.

If any of our relationships with these third party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, 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 to our pre-clinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced 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 peptide-based product candidates. As a result, our results of operations and the commercial prospects for our peptide-based product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. 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.

We rely completely on third parties to manufacture our drug substance and clinical drug product and we intend to rely on third parties to produce commercial supplies of any approved peptide-based product candidate.

Our clinical trials must be conducted with product manufactured under current good manufacturing practices and for Europe and other major countries, International Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines, and we rely on contract manufactures to manufacture and provide product for us that meet these requirements. We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our pre-clinical and clinical drug supplies and we lack the resources and the capability to manufacture any of our peptide-based product candidates on a clinical or commercial scale. We expect to continue to depend on contract manufacturers for the foreseeable future. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Moreover, our contract manufacturers are the sole source of supply for our clinical product candidates, including PTG-100. If we were to experience an unexpected loss of supply for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or termination of our clinical study and planned development program, or be required to restart or repeat, any ongoing clinical trials.

We also rely on our contract manufacturers to purchase from third party suppliers the materials necessary to produce our peptide-based product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our peptide-based product candidates for our clinical trials, and if approved, for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a peptide-based product candidate to complete the clinical trial, any significant delay in the supply of a peptide-based product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our peptide-based product candidates. If our contract manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our peptide-based product candidates, the commercial launch of our peptide-based product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our peptide-based product candidates.

If we submit an application for regulatory approval of any of our product candidates, the facilities used by our contract manufacturers to manufacture our product candidates will be subject to inspection and approval by the FDA or other regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our peptide-based product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our peptide-based product candidates, if approved.

We may fail to obtain orphan drug designations from the FDA for our product candidates, as applicable, and even if we obtain such designations, we may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Our strategy includes filing for orphan drug designation where available for our product candidates. Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug or biologic intended to treat a rare disease or condition, which is defined as one occurring in a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications, including a full NDA or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

We have not obtained nor have we sought to obtain orphan designation for any product candidates to date, although we believe some of the potential indications of our product candidates could qualify for orphan drug designation and the related benefits if approved for that indication. For example, if PTG-100 or PTG-200 is developed for the treatment of pediatric IBD or PTG-300 for the treatment of iron overload disorders in patients with transfusion-dependent ß-Thalassemia and possibly HH and SCD, we plan to file and expect to qualify for orphan drug designation with respect to such indication. Even if we obtain such designations, we may not be the first to obtain regulatory approval of a product candidate for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the orphan-designated disease or condition. Further, even if we obtain orphan drug designation exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may receive and be approved for the same condition, and only the first applicant to receive approval will receive the benefits of marketing exclusivity. Even after an orphan-designated product is approved, the FDA can subsequently approve a later drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek orphan drug designation for our product candidates, we may never receive such designations.

We may not be successful in obtaining or maintaining development and commercialization collaborations, and any potential partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

We have no current collaborations for any of our product candidates. Even if we are able to establish collaboration arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and growth prospects. While we currently plan to enter into collaborations that are limited to certain identified territories, there can be no assurance that we would maintain significant rights or control of future development and commercialization of such product candidate. Accordingly, if we collaborate with a third party for development and commercialization of a product candidate, we may relinquish some or all of the control over the future success of that product candidate to the third party, and that partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of the product candidate in the collaboration could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any potential collaboration or other arrangement that we may establish may not be favorable to us or may not be perceived as favorable, which may negatively impact the price of our common stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payments we receive from our partner may be insufficient to cover the cost of this development or may result in a dispute between the parties. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement and they may require substantial resources to maintain, which may be detrimental to the development of our other product candidates.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaboration arrangements to fail. Conflicts may arise between us and partners, such as conflicts concerning the implementation of development plans, efforts and resources dedicated to the product candidate, interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. If any such conflicts arise, a collaborator could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating sufficient revenue to achieve or maintain profitability:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaboration arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; or
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

In addition, the termination of a collaboration may limit our ability to obtain rights to the product or intellectual property developed by our collaborator under terms that would be sufficiently favorable for us to consider further development or investment in the terminated collaboration product candidate, even if it were returned to us.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have competitors worldwide, including major multinational pharmaceutical companies, biotechnology companies, specialty pharmaceutical and generic pharmaceutical companies as well as universities and other research institutions.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, and experienced marketing and manufacturing organizations. Mergers and acquisitions in our industry may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of newer technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, pharmaceutical products that are easier to develop, more effective or less costly than any product candidates that we are currently developing or that we may develop. If approved, our product candidates are expected to face competition from commercially available drugs as well as drugs that are in the development pipelines of our competitors.

Pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. If our competitors succeed in obtaining FDA, EMA or other regulatory approval or discovering, developing and commercializing drugs before we do or develop blocking intellectual property to which we do not have a license, there would be a material adverse impact on the future prospects for our product candidates and business.

In particular, we believe our principal competition in the treatment of IBD will come from companies with approved agents in the following therapeutic classes, among others:

- Infused α4ß7 antibody: Takeda Pharmaceutical Company
- Infused IL-23 and IL-12 antibody: Johnson & Johnson Services (Stelara® BLA filed in moderate-to-severe CD)
- Injectable or infused TNF-α antibody: Abbvie, Johnson & Johnson, Roche, UCB S.A.

We are also aware of several companies developing therapeutic product candidates for the treatment of IBD, including, but not limited to AstraZeneca, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene (mongersen sodium and ozanimod hydrochloride in Phase 3 clinical trials), Encycle Therapeutics, Genentech (etrolizumab in a Phase 3 clinical trial), Gilead Sciences (GS-5745 in a Phase 3 clinical trial), Pfizer (tofacitinib citrate in a Phase 3 clinical trial), and Roche.

We believe our principal competition in the treatment of iron overload disorders, such as ß-Thalassemia, HH and SCD, will come from other pipeline products being developed by companies such as Acceleron (luspatercept in a Phase 3 clinical trial), bluebird bio, Bristol-Myers Squibb, Emmaus Medical (glutamine in a Phase 3 clinical trial), Global Blood, La Jolla Pharmaceutical and Merganser Biotech, among others. We believe competition will also include approved iron chelation therapies that have been developed by Novartis and Apotex, among others.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our product candidates, in particular compared to marketed products and products in late-stage development;
- the time it takes for our product candidates to complete clinical development and receive regulatory approval, if at all;
- the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- the ability to protect intellectual property rights related to our product candidates;
- the ability to manufacture and sell commercial quantities of any of our product candidates that receive regulatory approval; and
- acceptance of any of our approved product candidates by physicians, payors and other healthcare providers.

Because our research approach depends on our proprietary technology platform, it may be difficult for us to continue to successfully compete in the face of rapid changes in technology. If we fail to continue to advance our technology platform, technological change may impair our ability to compete effectively and technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

We currently have no marketing and sales organization. To the extent any of our peptide-based product candidates for which we maintain commercial rights is approved for marketing, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our peptide-based product candidates, we may not be able to effectively market and sell any peptide-based product candidates, or generate product revenue.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any peptide-based product candidates that receive marketing approval, we would have to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development of any of our product candidates, we may elect to build a targeted specialty sales force which will be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. With respect to our peptide-based product candidates, we may choose to partner with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into collaborations with third parties for the commercialization of approved products, if any, on acceptable terms or at all, or if any such partner does not devote sufficient resources to the commercialization of our product or otherwise fails in commercialization efforts, we may not be able to successfully commercialize any of our peptide-based product candidates that receive regulatory approval. If we are not successful in commercializing our peptide-based product candidates, either on our own or through collaborations with one or more third parties, our future revenue will be materially and adversely impacted.

Even if our peptide-based product candidates receive marketing approval, they may fail to achieve market acceptance by physicians, patients, government payors (including Medicare and Medicaid programs), private insurers, and other third-party payors, or others in the medical community necessary for commercial success.

If any of our peptide-based product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, government payors, other third-party payors and other healthcare providers. If any of our approved peptide-based products fail to achieve an adequate level of acceptance, we may not generate significant revenue to become profitable. The degree of market acceptance, if approved for commercial sale, will depend on a number of factors, including but not limited to:

- the efficacy and potential advantages compared to alternative treatments;
- effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments;
- our ability to offer our peptide-based product candidates for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the willingness of the medical community to offer customers our peptide-based product candidates in addition to or in the place of current injectable therapies;
- the strength of marketing and distribution support;
- the availability of government and third-party coverage and adequate reimbursement;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our product candidates together with other medications.

Because we expect sales of our peptide-based product candidates, if approved, to generate revenue for us to achieve profitability, the failure of our peptide-based product candidates to achieve market acceptance would harm our business and could require us to seek collaborations or undertake additional financings sooner than we would otherwise plan.

We have focused our limited resources to pursue particular product candidates and indications, and consequently, we may fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

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

Even if we obtain and maintain approval for any of our product candidates from the FDA, we may never obtain approval for our product candidates outside of the United States, which would limit our market opportunities and adversely affect our business.

Sales of our product candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials and marketing approval and, to the extent that we retain commercial rights following clinical development, we would plan to seek regulatory approval to commercialize our peptide-based product candidates in the United States, the EU and additional foreign countries. Even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities of foreign countries must also approve the manufacturing and marketing of the product candidates in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the US, including additional pre-clinical studies or clinical trials. In many countries outside the US, a product candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that we intend to charge for our products is also subject to approval. We may decide to submit an MAA to the EMA for approval in the EEA. As with the FDA, obtaining approval of an MAA from the EMA is a similarly lengthy and expensive process and the EMA has its own procedures for approval of peptide-based product candidates. Even if a product is approved, the FDA or the EMA, as the case may be, may limit the indications for which the product may be marketed, require extensive warnings on the product labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the US and the EEA also have requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Also, regulatory approval for any of our peptide-based product candidates may be withdrawn. If we fail to comply with the regulatory requirements in international markets and or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our peptide-based product candidates will be harmed and our business will be adversely affected.

If we fail to comply with state and federal healthcare regulatory laws, we could face substantial penalties, damages, fines, disgorgement, exclusion from participation in governmental healthcare programs, and the curtailment of our operations, any of which could adversely affect our business, operations, and financial condition.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any future product candidates we may develop or any product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we would market, sell and distribute our products. 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. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying remuneration, directly or indirectly, in cash or in kind, in exchange for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- the federal false claims and civil monetary penalties laws, including the False Claims Act, which 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, claims for payment that are false, fictitious, or fraudulent; knowingly making, using, or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government; or knowingly making, using, or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;

- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes additional criminal and civil liability for, among other things, willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their implementing regulations, which also imposes obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal civil monetary penalties statute, which prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a Federal or state governmental program;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to certain payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members and payments or other "transfers of value" to such physician owners; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that 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 governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Further, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the ACA), among other things, amended the intent requirements of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity can now be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, ACA provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. Moreover, while we do not submit claims and our customers make the ultimate decision on how to submit claims, from time to time, we may provide reimbursement guidance to our customers. If a government authority were to conclude that we provided improper advice to our customers or encouraged the submission of false claims for reimbursement, we could face action against us by government authorities. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved. While we have worked to structure our arrangements to comply with applicable laws, because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use our product candidates, if approved, to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional onerous compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any peptide-based product candidates for which we obtain marketing approval.

For example, in the United States in March 2010, the ACA was enacted to increase access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and the health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The law has continued the downward pressure on pharmaceutical pricing, especially under the Medicare program, and increased the industry's regulatory burdens and operating costs. Among the provisions of the ACA of importance to our potential peptide-based product candidates are the following:

- an annual, non-tax deductible fee payable by any entity that manufactures or imports specified branded prescription drugs and biologic agents payable to the federal government based on each company's market share of prior year total sales of branded products to certain federal healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of manufacturers' Medicaid rebate liability to individuals enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs in certain states;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries under their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;

- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The financial impact of the ACA over the next few years will depend on a number of factors including but not limited to the policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2025 unless additional action is taken by Congress. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers and increased the statute of limitations period in which the government may recover overpayments to providers from three to five years. In addition, recently there has been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their commercial products. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates, if approved.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare therapies, which could result in reduced demand for our peptide-based product candidates or additional pricing pressures.

Legislative and regulatory proposals have also 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 marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. 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 coverage and reimbursement have been obtained. Reference pricing used by various countries and parallel distribution or arbitrage between low-priced and high-priced countries, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies, which is time-consuming and costly. If coverage and reimbursement of our product candidates are unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

Our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical and regulatory personnel. We are highly dependent on our existing senior management team, especially Dinesh V. Patel, Ph.D., our President and Chief Executive Officer, David Y. Liu, Ph.D., our Chief Scientific Officer and Head of Research and Development, Richard S. Shames, M.D., our Chief Medical Officer, Tom O'Neil, our Chief Financial Officer and William Hodder, our Senior Vice President of Corporate Development. We are not aware of any present intention of any of these individuals to leave us. In order to induce valuable employees to continue their employment with us, we have provided stock options that vest over time. The value to employees of stock options that vest over time is significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to maintain retention incentives or counteract more lucrative offers from other companies. All of our employees may terminate their employment with us at any time, with or without notice. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements would harm our research and development efforts as well as our business, financial condition and prospects. Our success also depends on our ability to continue to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management training and skills.

We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical, biotechnology, pharmaceutical and other businesses. Many of the other biopharmaceutical and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation or more diverse opportunities and better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize peptide-based product candidates and to grow our business and operations as currently contemplated.

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

As of June 30, 2016, we had 29 full-time employees. As our development and commercialization plans and strategies develop and operate as a public company, we expect to need additional managerial, operational, scientific, sales, marketing, development, regulatory, manufacturing, financial and other resources. Future growth would impose significant added responsibilities on members of management, including:

- designing and managing our clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our manufacturing and development efforts effectively;
- improving our managerial, development, operational and financial systems and controls; and
- expanding our facilities.

As our operations expand, we expect that we will need to manage relationships with strategic collaborators, CROs, contract manufacturers, suppliers, vendors and other third parties. Our future financial performance and our ability to develop and commercialize our peptide-based product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. We may not be successful in accomplishing these tasks in growing our company, and our failure to accomplish any of them could adversely affect our business and operations.

Significant disruptions of information technology systems or breaches of data security could adversely affect our business.

Our business is increasingly dependent on critical, complex and interdependent information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. The size and complexity of our internal computer systems and those of our CROs, contract manufacturers and other third parties on which we rely may make them potentially vulnerable to breakdown, telecommunications and electrical failures, malicious intrusion and computer viruses that may result in the impairment of key business processes. In addition, our systems are potentially vulnerable to data security breaches—whether by employees or others—that may expose sensitive data to unauthorized persons. Such data security breaches could lead to the loss of trade secrets or other intellectual property, or could lead to the public exposure of personally identifiable information (including sensitive personal information) of our employees, collaborators, clinical trial patients, and others. A data security breach or privacy violation that leads to disclosure or modification of or prevents access to patient information, including personally identifiable information or protected health information, could harm our reputation, compel us to comply with federal and/or state breach notification laws, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such data security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive patient data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Moreover, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information, trade secrets or other intellectual property. While we have implemented security measures to protect our data security and information technology systems, such measures may not prevent such events. Any such disruptions and breaches of security could have a material adverse effect on the development of our product candidates as well as our business and financial condition.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

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

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

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. 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 employees, independent contractors, principal investigators, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, independent contractors, principal investigators, consultants and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information to the FDA, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations established and enforced by comparable foreign regulatory authorities, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, creating fraudulent data in our pre-clinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and third-parties, 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. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. 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.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any of our peptide-based product candidates, if approved.

We face an inherent risk of product liability as a result of the clinical testing of our peptide-based product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to stop development or, if approved, limit commercialization of our peptide-based product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical studies;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- decreased demand for our peptide-based product candidates;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue from product sales; and
- the inability to commercialize any our peptide-based product candidates, if approved.

Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the development or commercialization of our peptide-based product candidates. We currently carry clinical trial liability insurance for our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

We currently conduct, and intend to continue to conduct a substantial portion of the clinical trials for our product candidates outside of the United States. If approved, we may commercialize our product candidates abroad. We will thus be subject to the risks of doing business outside of the United States.

We currently conduct, and intend to continue to conduct, a substantial portion of our clinical trials outside of the United States and, if approved, we intend to also market our peptide-based product candidates outside of the United States. We are thus subject to risks associated with doing business outside of the United States. With respect to our peptide-based product candidates, we may choose to partner with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems outside of the United States or in lieu of our own sales force and distribution systems, which would indirectly expose us to these risks. Our business and financial results in the future could be adversely affected due to a variety of factors associated with conducting development and marketing of our peptide-based product candidates, if approved, outside of the United States, including:

- Medical standard of care and diagnostic criteria may differ in foreign jurisdictions, which may impact our ability to enroll and successfully complete trials designed for U.S. marketing;
- efforts to develop an international sales, marketing and distribution organization may increase our expenses, divert our management's attention from the acquisition or development of peptide-based product candidates or cause us to forgo profitable licensing opportunities in these geographies;
- changes in a specific country's or region's political and cultural climate or economic condition;
- unexpected changes in foreign laws and regulatory requirements;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- inadequate intellectual property protection in foreign countries;
- trade-protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the US Department of Commerce and fines, penalties or suspension or revocation of export privileges;
- regulations under the U.S. Foreign Corrupt Practices Act and similar foreign anti-corruption laws;
- the effects of applicable foreign tax structures and potentially adverse tax consequences; and
- significant adverse changes in foreign currency exchange rates which could make the cost of our clinical trials, to the extent conducted outside of the US, more expensive.

Our headquarters and certain of our data storage facilities are located near known earthquake fault zones. The occurrence of an earthquake, fire or any other catastrophic event could disrupt our operations or the operations of third parties who provide vital support functions to us, which could have a material adverse effect on our business and financial condition.

We and some of the third party service providers on which we depend for various support functions, such as data storage, are vulnerable to damage from catastrophic events, such as power loss, natural disasters, terrorism and similar unforeseen events beyond our control. Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires.

We do not carry earthquake insurance. Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, damaged critical infrastructure, such as our data storage facilities or financial systems, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery and business continuity plan in place. We may incur substantial expenses as a result of the absence or limited nature of our internal or third party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our development plans and business.

The insurance coverage and reimbursement status of newly-approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our peptide-based product candidates could limit our ability to generate revenue.

The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford medications and therapies. Sales of any of our peptide-based product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our peptide-based product candidates will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain adequate pricing that will allow us to realize a sufficient return on our investment.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the United States Department of Health and Human Services. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare. Private payors tend to follow CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel products such as ours since there is no body of established practices and precedents for these new products. Reimbursement agencies in Europe may be more conservative than CMS.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries may cause us to price our tablet vaccine candidates on less favorable terms than we currently anticipate. In many countries, particularly the countries of the European Union, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our peptide-based product candidates to other available therapies. In general, the prices of products under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our peptide-based product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits.

Moreover, increasing efforts by governmental and third-party payors, in the United States and internationally, to cap or reduce healthcare costs may cause such organizations to limit both coverage and level of reimbursement for new products approved and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of any of our tablet vaccine candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products into the healthcare market.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates and technologies, we may not be able to compete effectively in our markets.

We rely upon a combination of patent protection, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions. The patent applications that we own or license may fail to result in issued patents in the United States or in other foreign countries, or they may fail to result in issued patents with claims that cover our product candidates or technologies in the United States or in other foreign countries. There is no assurance that all the potentially relevant prior art relating to our patent and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents have been issued, or do successfully issue, from our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patent and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates and technologies, or prevent others from designing around our claims.

If the breadth or strength of protection provided by the patent and patent applications we hold, obtain or pursue with respect to our product candidates and technologies is challenged, or if they fail to provide meaningful exclusivity for our product candidates and technologies, it could threaten our ability to commercialize our product candidates and technologies. Several patent applications covering our product candidates and technologies have been filed recently. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent, or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Any successful opposition to these patents or any other patents owned by or, if applicable in the future, licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates and technologies that we may develop. Further, if we encounter delays in our clinical trials or in gaining regulatory approval, the period of time during which we could market any of our product candidates under patent protection, if approved, would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidates and technologies. Furthermore, an interference proceeding can be provoked by a third party or instituted by the U.S. Patent and Trademark Office (PTO) to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available however the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

If, in the future, we obtain licenses from third parties, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications or to maintain any patents, covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, if we do obtain necessary licenses, we will likely have obligations under those licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

If we are unable to protect the confidentiality of our trade secrets and proprietary know-how or if competitors independently develop viable competing products, our business and competitive position may be harmed.

While we hold one issued patent and have filed patent applications to protect certain aspects of our product candidates, we also rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. For example, we primarily rely on trade secrets and confidentiality agreements to protect our peptide therapeutics technology platform. 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 our market.

We seek to protect our proprietary information, data and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. Although these agreements are designed to protect our proprietary information, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Although we require all of our employees to assign their inventions to us, and endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how and other confidential information related to such technology, we cannot be certain that we have executed such agreements with all third parties who may have helped to develop our intellectual property or who had access to our proprietary information, nor can be we certain that our agreements will not be breached. If any of the parties to these confidentiality agreements breaches or violates the terms of such agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result.

We also seek to preserve the integrity and confidentiality of our data, trade secrets and know-how by maintaining physical security of our premises and physical and electronic security of our information technology systems. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that our trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to our trade secrets.

Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. We cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Even if we are able to adequately protect our trade secrets and proprietary information, our trade secrets could otherwise become known or could be independently discovered by our competitors. Competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, in the absence of patent protection, we would have no right to prevent them, or those to whom they communicate, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products, others may be able to exploit our proprietary peptide product candidate discovery technologies to identify and develop competing product candidates, and thus our competitive position could be adversely affected, as could our business.

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

Competitors may infringe our issued patent or any patents issued as a result of our pending or future patent applications. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our patent applications at risk of not yielding an issued patent.

Interference proceedings provoked by third parties or brought by us, the PTO or any foreign patent authority may be necessary to determine the priority of inventions with respect to our patent or patent applications. An unfavorable outcome could require us to cease using the related technology 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 a license on commercially reasonable terms, if any license is offered at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

We may not be able to prevent misappropriation of our intellectual property, trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. 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 our common stock.

Any issued patents covering our product candidates, including any patent that may issue as a result of our pending or future patent applications, could be found invalid or unenforceable if challenged in court in the United States or abroad.

If we initiate legal proceedings against a third party to enforce a patent covering our product candidates or technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the PTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post grant review, and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates or technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

The lives of any patents issued as a result of our pending or future patent applications may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2022 to 2035. In addition, although upon issuance in the United States the life of a patent can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected.

Competitors could enter the market with generic versions of our product candidates, which may result in a material decline in sales of our product candidates.

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's finding of safety and effectiveness of a previously approved drug. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Innovative small molecule drugs may be eligible for certain periods of regulatory exclusivity (e.g., five years for new chemical entities, three years for changes to an approved drug requiring a new clinical study, seven years for orphan drugs), which preclude FDA approval (or in some circumstances, FDA filing and review of) an ANDA or 505(b)(2) NDA relying on the FDA's finding of safety and effectiveness for the innovative drug. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic applicant that seeks to market its product before expiration of the patents must include in the ANDA or 505(b)(2) what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if our product candidates are approved, competitors could file ANDAs for generic versions of our product candidates, or 505(b)(2) NDAs that reference our product candidates. If there are patents listed for our product candidates in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could more immediately face generic competition and its sales would likely decline materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected.

Third party claims of intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing or otherwise violating the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, derivation proceedings, post grant reviews, inter partes reviews, and reexamination proceedings before the PTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and 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 manufacture of our product candidates and technologies. Third parties, including our competitors may initiate legal proceedings against us alleging that we are infringing or otherwise violating their patent or other intellectual property rights. Given the vast number of patents in our field of technology, we cannot assure you that marketing of our product candidates or practice of our technologies will not infringe existing patents or patents that may be granted in the future. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending of which we are unaware that may later result in issued patents that may be infringed by the practice of our peptide therapeutics technology platform or the manufacture, use or sale of our product candidates. If a patent holder believes our product candidates or technologies infringe on its patent, the patent holder may sue us even if we have received patent protection for our product candidates and technologies. In addition, third parties may obtain patents in the future and claim that our product candidates or technologies infringe upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product or formulation itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates or technologies may give rise to claims of infringement of the patent rights of others.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further practice our technologies or develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. Even if we are successful in defending against any infringement claims, litigation is expensive and time-consuming and is likely to divert management's attention and substantial resources from our core business, which could harm our 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 for willful infringement (which may include situations in which we had knowledge of an issued patent but nonetheless proceeded with activity which infringed such patent), limit our uses, pay royalties or redesign our infringing product candidates, which may be impossible or require substantial time and monetary expenditure. We may choose to seek, or may be required to seek, a license from the third-party patent holder and would most likely be required to pay license fees or royalties or both, each of which could be substantial. These licenses may not be available on commercially reasonable terms, however, or at all. Even if we were able to obtain a license, the rights we obtain may be nonexclusive, which would provide our competitors access to the same intellectual property rights upon which we are forced to rely. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In such an event, we would be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could harm our business significantly.

We may not identify relevant third party patents or may incorrectly interpret the relevance, scope or expiration of a third party patent which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent, any patents that may be issued on as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our shareholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

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

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Filing, prosecuting and defending patents on all of our product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The requirements for patentability differ, in varying degrees, from country to country. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patent and other intellectual property rights, especially those relating to life sciences. In addition, the laws of some foreign countries do not protect intellectual property rights, including trade secrets, to the same extent as federal and state laws of the United States. This could make it difficult for us to stop the infringement of any patents we obtain or the misappropriation of our other intellectual property rights. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Proceedings to enforce our patent rights in foreign jurisdictions, regardless of whether successful, would result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets.

Competitors may use our 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 have patent protection but enforcement is not as strong as in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or 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 to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business.

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

The PTO and various non-US governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the PTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ reputable law firms and other professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patent and patent applications that we own, and if we in-license intellectual property we may have to rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

On September 16, 2011, the Leahy-Smith America Invents Act (Leahy-Smith Act) was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The PTO is currently developing 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, did not become effective until March 2013, 18 months after its enactment. 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 patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. Depending on decisions by the U.S. Congress, the federal courts, and the PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and patents that we might obtain in the future.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our issued patent or any pending patent application we may have;
- we might not have been the first to make the inventions covered by the issued patent or pending patent application that we own;
- we might not have been the first to file patent applications covering an invention;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- pending patent applications that we own or license may not lead to issued patents;
- the issued patent that we own or any issued patents that we license may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of former or other employers.

Many of our employees and consultants, including our senior management and our scientific founders, have been employed or retained at universities or by other biotechnology or pharmaceutical companies, including potential competitors. Some of our employees and consultants, including each member of our senior management and each of our scientific founders, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment or retention. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's or consultant's former or other employer. We are not aware of any threatened or pending claims related to these matters or concerning the agreements with our senior management or scientific founders, 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.

We may be subject to claims challenging the inventorship or ownership of our issued patent, any patents issued as a result of our pending or future patent applications and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our issued patent, any patents issued as a result of our pending or future applications or other intellectual property. For example, we work with third-party contractors in formulating and manufacturing our product candidates. While we believe we have all rights to any intellectual property related to our product candidates, a third party-contractor may claim they have ownership rights. We have had in the past, and we may also have in the future, ownership disputes arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates and technologies. For example, some of our consultants are employees of the University of Queensland. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We have not yet registered trademarks for a commercial trade name for our product candidates and failure to secure such registrations could adversely affect our business.

We have not yet registered trademarks for a commercial trade name for our product candidates. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the PTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We may find that our programs require the use of proprietary rights held by third parties or the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. Even if we are able to obtain a license to intellectual property of interest, we may not be able to secure exclusive rights, in which case others could use the same rights and compete with us.

If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our product candidates.

We may seek collaboration arrangements with pharmaceutical or biotechnology companies for the development or commercialization of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. We will face, to the extent that we decide to enter into collaboration agreements, significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we so chose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to us.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks Related to Ownership of our Common Stock

The price of our stock may be volatile, and you could lose all or part of your investment.*

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in these "Risk Factors" and elsewhere in this quarterly report, these factors include, but are not limited to:

- any delay in the commencement, enrollment and ultimate completion of clinical trials;
- actual or anticipated results in our clinical trials or those of our competitors;
- positive outcomes, or faster development results than expected, by parties developing peptide-based product candidates that are competitive with our peptide-based product candidates, as well as approval of any such competitive peptide-based product candidates;
- failure to successfully develop commercial-scale manufacturing capabilities;
- unanticipated serious safety concerns related to the use of any of our peptide-based product candidates;
- failure to secure collaboration agreements for our peptide-based product candidates or actual or perceived unfavorable terms of such agreements;

- adverse regulatory decisions;
- changes in the structure of healthcare payment systems;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our peptide-based product candidates;
- our dependence on third parties, including CROs as well as manufacturers;
- our failure to successfully commercialize any of our peptide-based product candidates, if approved;
- additions or departures of key scientific or management personnel;
- failure to meet or exceed any financial guidance or development timelines that we may provide to the public;
- actual or anticipated variations in quarterly operating results;
- failure to meet or exceed the estimates and projections of the investment community;
- overall performance of the equity markets and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies;
- conditions or trends in the biotechnology and biopharmaceutical industries;
- announcements of significant acquisitions, strategic collaborations, joint ventures or capital commitments by us or our competitors;
- our ability to maintain an adequate rate of growth and manage such growth;
- issuances of debt or equity securities;
- significant lawsuits, including patent or stockholder litigation;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- ineffectiveness of our internal controls;
- general political and economic conditions; and
- effects of natural or man-made catastrophic events.

In addition, the stock market in general, and The NASDAQ Global Market 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 the above 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.

Volatility in our share price could subject us to securities class action litigation.

Securities class action litigations have often been brought against companies following a decline in the market price of their securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could 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 August 31, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 39% of our stock. Therefore, these stockholders will have substantial influence and may be able to determine 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 concentration of voting power could, among other things, delay or prevent an acquisition of our company on terms that other stockholders may desire, which in turn could depress our stock price and may prevent attempts by our stockholders to replace or remove the board of directors or management.

We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.

Prior to the IPO, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and procedures. In connection with the audit of our consolidated financial statements for the years ended December 31, 2014 and 2015, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting. 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 our annual or interim financial statements will not be prevented or detected on a timely basis.

The first material weakness related to a deficiency in the operation of our internal controls over the accounting for non-routine, complex equity transactions, which resulted in material post-closing adjustments to the convertible preferred stock, additional paid-in capital, interest expense, and gain from modification of the redeemable convertible preferred stock balances in the consolidated financial statements for the year ended December 31, 2013. Our lack of adequate accounting personnel has resulted in the identification of a second material weakness in our internal control over financial reporting for the years ended December 31, 2014 and 2015. Specifically, we did not, and have not historically, appropriately designed and implemented controls over the review and approval of manual journal entries and the related supporting journal entry calculations.

Neither we nor our independent registered public accounting firm has performed or was required to perform an evaluation of our internal control over financial reporting in according with Section 404 of the Sarbanes-Oxley Act. We intend to take steps to remediate the material weaknesses, including increasing the depth and experience within our accounting and finance organization, as well as designing and implementing improved processes and internal controls. While we intend to implement a plan to remediate the material weaknesses, we are in the early phases of the implementation of this plan. We cannot predict the success of such plan or the outcome of our assessment of these plans at this time. We can give no assurance that this implementation will remediate this deficiency in internal control or that additional material weaknesses or significant deficiencies in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations.

We are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.*

We will be required, pursuant to Section 404 of the Sarbanes-Oxley Act (Section 404), to furnish a report by management on the effectiveness of our internal control over financial reporting for the first fiscal year beginning after the effective date of the IPO. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered accounting firm.

We are beginning the costly and challenging process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404, and we may not be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404.

During our evaluation of our internal control, if we identify one or more material weaknesses in our internal control over financial reporting or fail to remediate our current material weaknesses, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our ordinary shares could decline, and we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

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

We are an "emerging growth company" as defined in the JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We will remain an emerging growth company, and thus may continue to rely on these exemptions, until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of the IPO, (b) in which we have total annual gross revenue of at least $1.0 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under Section 107(b) of the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not "emerging growth companies."

Future sales of our common stock may depress our share price.*

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. At August 31, 2016, we had outstanding a total of 16,461,481 shares of common stock. Of these shares, approximately 8,959,495 million shares of our common stock are currently restricted as a result of securities laws or lock-up agreements but will be able to be sold upon expiration of the lockup period in February 2017. In addition, as of June 30, 2016, 1,309,845 shares of common stock that are subject to outstanding options, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Any sales of securities by these stockholders could have an adverse effect on the trading price of our common stock. In addition, in the future we may issue common stock or other securities if we need to raise additional capital. The number of our new common stock issued in connection with raising additional capital could constitute a material portion of our then outstanding common stock.

If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to maintain compliance with our public company responsibilities and corporate governance practices.

We will incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Securities Exchange Act of 1934, as amended (the Exchange Act), and regulations regarding corporate governance practices. The listing requirements of The NASDAQ Global Market require that we satisfy certain corporate governance requirements relating to director independence, distributing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel will need to devote a substantial amount of time to ensure that we comply with all of these requirements, and we will likely need to hire additional accounting and financial staff with appropriate public company reporting experience and technical accounting knowledge. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time consuming and costly. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors' and officers' insurance, on acceptable terms.

As a public company, and particularly after we are no longer an "emerging growth company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The NASDAQ Global Market and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our board of directors. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

To date, we have only conducted a preliminary review of certain of our internal controls for the purpose of providing the reports required by these rules. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we will be required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The NASDAQ Global Market or other adverse consequences that would materially harm our business.

NASDAQ may delist our securities from its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.*

Our common stock is listed on The NASDAQ Global Market. We cannot assure you that, in the future, our securities will meet the continued listing requirements to be listed on The NASDAQ Global Market. If The NASDAQ Global Market delists our common stock, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

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 will be influenced by the research and reports that securities or industry analysts publish about us or our business. In the event one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price could be adversely affected. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, and we could lose visibility in the financial markets, which might cause our stock price and trading volume to decline.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third party claims against us and may reduce the amount of money available to us generally.

Our amended and restated certificate of incorporation provides that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into and will enter into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

As a result, if we are required to indemnify one or more of our directors or executive officers, it may reduce our available funds to satisfy successful third party claims against us, may reduce the amount of money available to us and may have a material adverse effect on our business and financial condition.

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

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

Provisions in our corporate charter documents could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, 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. Because our board of directors is responsible for appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.*

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Our board of directors has certain characteristics which may delay or prevent a change of our management or a change in control.

Our board of directors has the following characteristics which may delay or prevent a change of management or a change in control:

- our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- our stockholders may not act by written consent or call special stockholders' meetings; as a result, a holder, or holders, controlling a majority of our capital stock would not be able to take certain actions other than at annual stockholders' meetings or special stockholders' meetings called by the board of directors, the chairman of the board or the chief executive officer;
- our certificate of incorporation does not provide for cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- stockholders must provide advance notice and additional disclosures in order to nominate individuals for election to the board of directors or to propose matters that can be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of our company; and
- our board of directors may issue, without stockholder approval, shares of undesignated preferred stock; the ability to issue undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to acquire us.

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

We have incurred substantial losses during our history. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, 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. Under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage points change (by value) in its equity ownership over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We have not completed our analysis to determine what, if any, impact any prior ownership change has had on our ability to utilize our net operating loss carryforwards. In addition, we may experience ownership changes in the future or subsequent shifts in our stock ownership, some of which are outside our control. As of December 31, 2015, we had federal net operating loss carryforwards of approximately $20.0 million that could be limited if we have experienced, or if in the future we experience, an ownership change, which could have an adverse effect on our future results of operations.

Provisions under Delaware law and California law could make an acquisition of our company more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any holder of at least 15% of our capital stock for a period of three years following the date on which the stockholder acquired at least 15% of our common stock. Likewise, because our principal executive offices are located in California, the anti-takeover provisions of the California Corporations Code may apply to us under certain circumstances now or in the future.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Sale of Unregistered Securities

From April 1, 2016 to June 30, 2016, we granted stock options to purchase an aggregate of 526,500 shares of common stock at an exercise price of $4.205 to a total of 36 employees, directors and consultants under our 2007 Stock Option and Incentive Plan. From April 1, 2016 to June 30, 2016, no options to purchase shares of common stock were exercised.

In May 2016, we issued an aggregate of 1,999,998 shares of Series B redeemable convertible preferred stock (convertible into 137,930 shares of common stock) pursuant to the cash exercise of warrants to purchase shares of our Series B convertible preferred stock at an exercise price of $0.01 per share. We received cash proceeds of $20,000 from the exercise of such warrants. These warrants were issued to three accredited investors.

The offers, sales and issuances of the securities described in paragraph (1) above were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 thereunder as offers and sale of securities pursuant to certain compensatory benefit plans and contracts relating to compensation in compliance with Rule 701.

The offer, sale, and issuance of the securities described in paragraph (2) above was deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as a transaction by an issuer not involving a public offering. The recipients of securities in these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in this transaction. The recipients of securities in these transactions were accredited investors and had adequate access, through employment, business or other relationships, to information about us.

Use of Proceeds from our Public Offering of Common Stock

On August 10, 2016, our registration statements on Form S-1 (File Nos. 333-212476 and 333-213071) relating to the IPO became effective. The IPO closed on August 16, 2016 at which time we issued 7,500,000 shares of our common stock at an initial offering price of $12.00 per share. We received net proceeds from the IPO of approximately $83.7 million, after deducting underwriting discounts of approximately $6.3 million, but before deducting offering costs paid by us. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates, or to our affiliates.

Leerink Partners LLC, Barclays Capital Inc. and BMO Capital Markets Corp. acted as the underwriters. Shares of our common stock began trading on the NASDAQ Global Market on August 11, 2016. The shares were registered under the Securities Act on registration statements on Form S-1 (File Nos. 333-212476 and 333-213071).There has been no material change in the planned use of proceeds from our IPO from that described in the prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on August 10, 2016.

Repurchases of Shares or of Company Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

See the Exhibit Index on the page immediately following the signature page to this Quarterly Report on Form 10-Q for a list of the exhibits filed as part of this Quarterly Report, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

PROTAGONIST THERAPEUTICS, INC.

Date: September 15, 2016

By: /s/ Dinesh V. Patel, Ph.D.
Dinesh V. Patel, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer) PEO

Date: September 15, 2016

By: /s/ Thomas P. O'Neil
Thomas P. O'Neil
Chief Financial Officer
(*Principal Financial PF and Accounting Officer AO*)

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation	8-K	001-3785237852	3.1	08/16/2016
3.2	Amended and Restated Bylaws	S-1/A	333-212476	3.2	08/01/2016
4.1	Specimen stock certificate evidencing the shares of common stock	S-1/A	333-212476	4.1	08/01/2016
4.2	Amended and Restated Investor Rights Agreement, by and among Protagonist Therapeutics, Inc. and the stockholders named therein, dated July 10, 2015.	S-1/A	333-212476	4.2	08/01/2016
10.1	Protagonist Therapeutics, Inc. 2007 Stock Option and Incentive Plan, as amended and restated, and form of option agreement, exercise notice, joinder, and adoption agreement thereunder.	S-1/A	333-212476	10.1	08/01/2016
10.2	Protagonist Therapeutics, Inc. 2016 Equity Incentive Plan and forms of stock option grant notice, option agreement, notice of exercise, restricted stock unit grant notice and restricted stock unit agreement thereunder.	S-8	333-213120	99.2	08/15/2016
10.3	Protagonist Therapeutics, Inc. 2016 Employee Stock Purchase Plan.	S-1/A	333-212476	10.3	08/01/2016
10.4	Form of Indemnity Agreement for Directors and Officers.	S-1/A	333-212476	10.4	08/01/2016
10.5	Third Amendment to Lease, dated August 11, 2015, by and between the Registrant and Berrueta Family L.P.	S-1/A	333-212476	10.8	08/01/2016
10.6	Severance Agreement, dated August 1, 2016, by and between the Registrant and Dinesh Patel.	S-1/A	333-212476	10.9	08/01/2016
10.7	Severance Agreement, dated August 1, 2016, by and between the Registrant and David Y. Liu, Ph.D.	S-1/A	333-212476	10.10	08/01/2016
10.8	Severance Agreement, dated August 1, 2016, by and between the Registrant and William Hodder.	S-1/A	333-212476	10.11	08/01/2016
10.9	Severance Agreement, dated August 1, 2016, by and between the Registrant and Tom O'Neil.	S-1/A	333-212476	10.12	08/01/2016
10.10	Severance Agreement, dated August 1, 2016, by and between the Registrant and Richard Shames, M.D.	S-1/A	333-212476	10.13	08/01/2016
10.11	Fourth Amendment to Lease, dated April 27, 2016, by and between the Registrant and Berrueta Family L.P.				
31.1+	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2+	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1+*	Certification of Chief Executive Officer and Chief Financial Officer, as required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS+	XBRL Instance Document				
101.SCH+	XBRL Taxonomy Extension Schema Document				
101.CAL+	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF+	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB+	XBRL Taxonomy Extension Labels Linkbase Document				
101.PRE+	XBRL Taxonomy Extension Presentation Linkbase Document				

+ Filed herewith

* This certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Protagonist Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of the Form 10-Q, irrespective of any general incorporation language contained in such filing.

Exhibit 10.11

FOURTH AMENDMENT TO LEASE

THIS FOURTH AMENDMENT TO LEASE (this "Amendment") is dated as of April 27, 2016 (the "Effective Date"), by and between Berrueta Family L.P., a California limited partnership ("Landlord") and Protagonist Therapeutics, Inc., a Delaware corporation ("Tenant"), with reference to the following facts and objectives:

RECITALS

A. Landlord and Tenant entered into that certain Lease, dated as of September 30, 2013 (the "Initial Lease"), as amended by that certain First Amendment to Lease dated as of March 24, 2014, that certain Second Amendment to Lease dated as of May 4, 2015 and that certain Third Amendment to Lease dated as of August 11, 2015, pertaining to certain premises located at 521 Cottonwood Drive, Milpitas, California. Pursuant to the Lease, Landlord has leased to Tenant space currently containing approximately 10,293 rentable square feet (the "Existing Premises").

B. Landlord and Tenant desire to amend the Lease to, among other things, expand the Premises as defined in the Lease to include additional space in the Building, consisting of approximately 1,079 rentable square feet, as shown on Exhibit A attached hereto (the "Additional Space"). The Initial Lease, as amended, shall be referred to as the "Lease".

AGREEMENT

NOW, THEREFORE, in consideration of good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Effective Date. The terms of this Amendment shall be effective on the Effective Date.

2. Expansion. Effective one (1) day following full execution and delivery of this Amendment by Landlord and Tenant (the "Additional Space Commencement Date") and throughout the remainder of the Term, the Premises shall include the Additional Space, the square footage of the Premises shall be increased by 1,079 rentable square feet to 11,372 rentable square feet, and the Existing Premises and the Additional Space shall collectively be deemed the Premises. On the Additional Space Commencement Date, the Additional Space shall be delivered to Tenant and in its as-is condition, and Tenant shall not be entitled to receive, with respect to the Additional Space, any allowance, free rent or other financial concession granted with respect to the Existing Premises. Notwithstanding the foregoing, any delay in delivery of the Additional Space beyond the Additional Space Commencement Date shall result in a postponement of Tenant's obligation to pay Rent with respect to the Additional Premises until such delivery, but shall not otherwise subject Landlord to any liability for loss or damage resulting therefrom.

3. Tenant's Share. Commencing on the Additional Space Commencement Date, Tenant's Share of the Building shall be increased by a sum equal to 1.62%.

4. Base Rent. Effective as of the Additional Space Commencement Date and throughout the remainder of the Term, the Base Rent schedule on the first page of the Lease shall be changed to the following:

May 1, 2016 – April 30, 2017:	$34,570.88

May 1, 2017 – August 31, 2017:	$35,608.01
September 1, 2017 – April 30, 2018:	$21,844.27

5. Security Deposit. The Security Deposit is hereby increased by Three Thousand One Hundred Eighty Three Dollars and Five Cents ($3,183.05) and Tenant shall deliver such amount to Landlord concurrently herewith.

6. Disproportionate Use of Utilities. Landlord and Tenant acknowledge and agree that Tenant intends to operate a vivarium in the Additional Space that will involve a disproportionate and after-hours usage of utilities. Tenant shall pay the cost of such disproportionate and after-hours usage of utilities as reasonably determined in good faith by Landlord from time to time within twenty (20) days of request by Landlord. If Tenant reasonably disagrees with Landlord's determination of such disproportionate and after-hours usage, without relieving Tenant of its obligation to timely make such payment, Tenant may notify Landlord of such disagreement and Landlord will promptly share its methodology and relevant data with Tenant and negotiate in good faith with Tenant to make appropriate adjustments based on errors in Landlord's determination accurately identified by Tenant. Landlord shall promptly refund to Tenant any overpayment agreed upon by the parties.

7. Miscellaneous. This Amendment, together with the Lease, constitutes the entire agreement between Landlord and Tenant regarding the Lease and the subject matter contained herein and supersedes any and all prior and/or contemporaneous oral or written negotiations, agreements or understandings. This Amendment shall be binding upon and inure to the benefit of Landlord and Tenant and their respective heirs, legal representatives, successors and assigns. No subsequent change or addition to this Amendment shall be binding unless in writing and duly executed by both Landlord and Tenant. Except as specifically amended hereby, all of the terms and conditions of the Lease are and shall remain in full force and effect and are hereby ratified and confirmed. Capitalized terms used but not defined in this Amendment shall have the meanings ascribed to such terms in the Lease. This Amendment may be executed in one or more counterparts, each of which shall be an original, but all of which, taken together, shall constitute one and the same Amendment. This Amendment may be delivered to the other party hereto by facsimile or email transmission of a copy of this Amendment bearing the signature of the party so delivering this Amendment.

[*SIGNATURE PAGE TO FOLLOW*]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the day first above written.

LANDLORD:

BERRUETA FAMILY L.P.,
a California limited partnership

By: 

Name: MARIA BERRUETA

Its: PARTNER

TENANT:

PROTAGONIST THERAPEUTICS, INC.,
a Delaware corporation

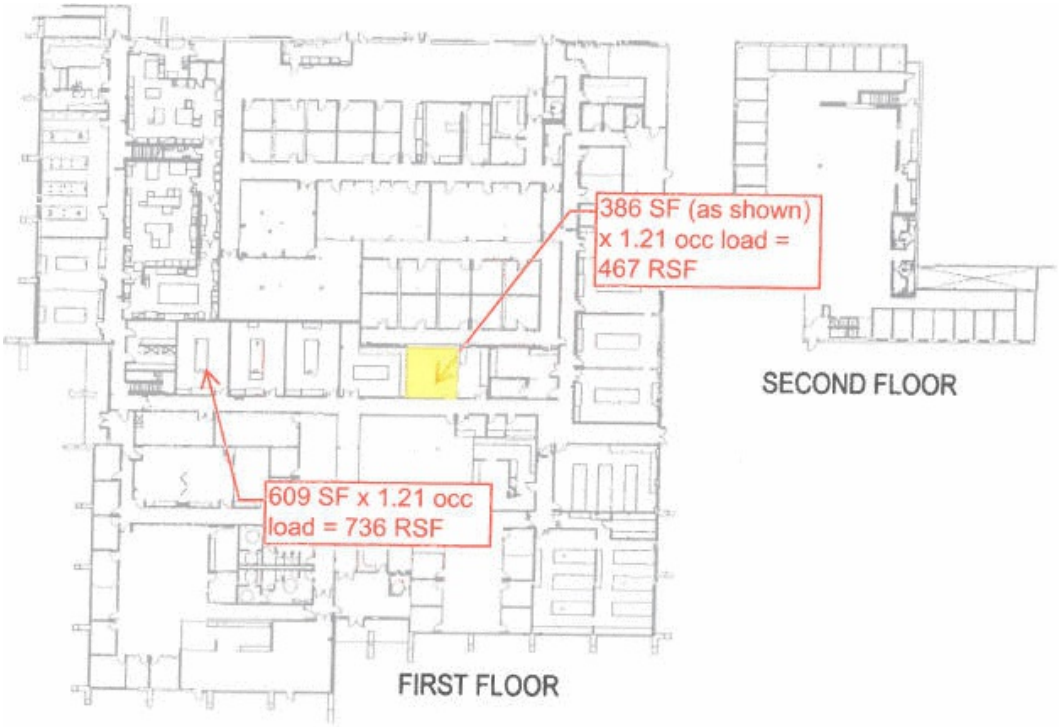
By: 

Name: Dinesh V. Patel

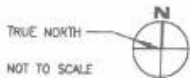
Its: CEO & President

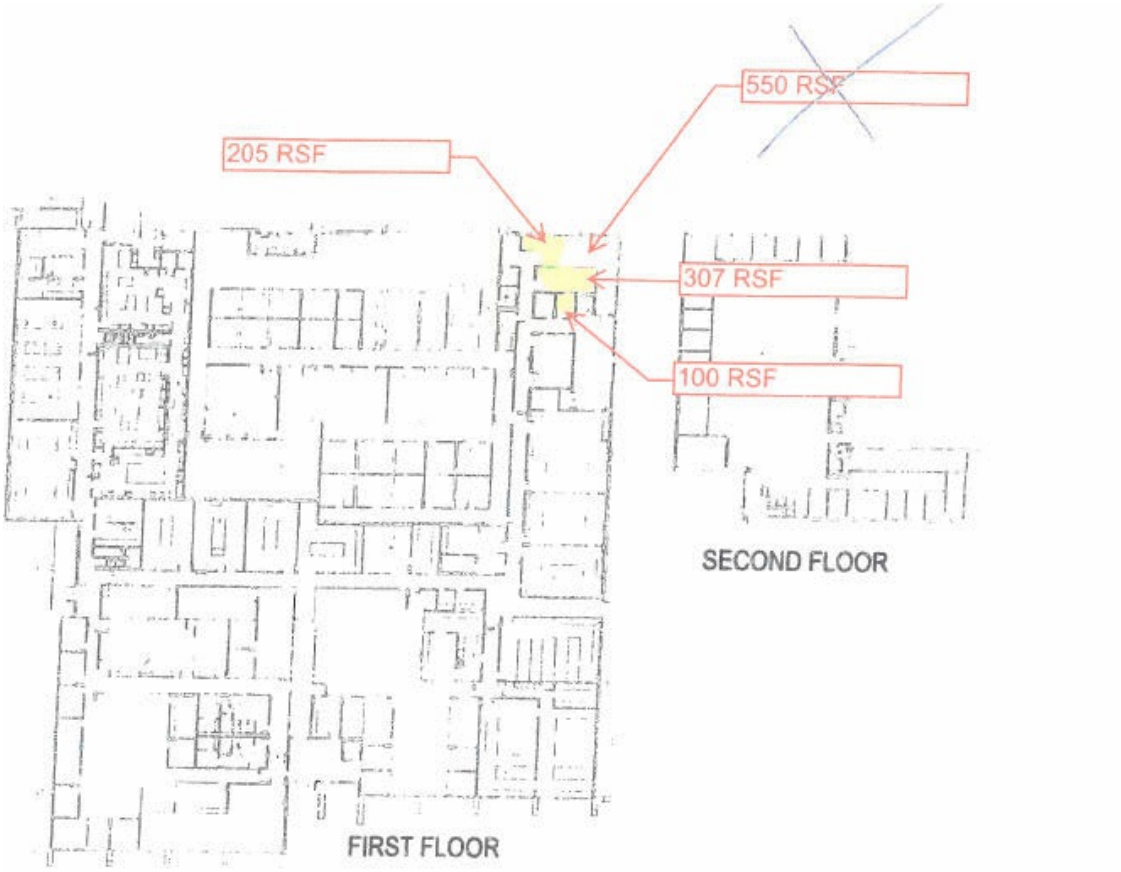
EXHIBIT A

Additional Space



521 COTTONWOOD DRIVE
MILPITAS, CA. 95035





521 COTTONWOOD DRIVE
MILPITAS, CA. 95035

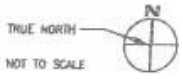


Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Dinesh V. Patel, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Protagonist Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 15, 2016

/s/ Dinesh V. Patel, Ph.D.
Dinesh V. Patel, Ph.D.
President, Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Thomas P. O'Neil, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Protagonist Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and we have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: September 15, 2016

/s/ Thomas P. O'Neil
Thomas P. O'Neil
Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Dinesh V. Patel, Chief Executive Officer of Protagonist Therapeutics, Inc. (the "Company"), and Thomas P. O'Neil, Chief Financial Officer of the Company, each hereby certify that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended June 30, 2016, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act of 1934, as amended; and

2. The information contained in the Periodic Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Dinesh V. Patel, Ph.D.

Date: September 15, 2016

Dinesh V. Patel, Ph.D.
President, Chief Executive Officer

/s/ Thomas P. O'Neil

Date: September 15, 2016

Thomas P. O'Neil
Chief Financial Officer

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Protagonist Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.