CASCADIAN THERAPEUTICS, INC.

FORM 10-Q
(Quarterly Report)

Filed 11/08/17 for the Period Ending 09/30/17

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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2017

or

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

For the transition period from to

Commission file number: 001-33882

CASCADIAN THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**26-0868560**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
2601 Fourth Ave., Suite 500 Seattle, Washington	**98121**
(Address of principal executive offices)	**(Zip Code)**

(206) 801-2100
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, 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. (Check one):

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 8, 2017, the number of outstanding shares of the registrant's common stock, par value $0.0001 per share, was 50,560,320.

CASCADIAN THERAPEUTICS, INC.

FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2017

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

CASCADIAN THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	September 30, 2017	December 31, 2016
	(Unaudited)	
ASSETS		
Current:		
Cash and cash equivalents	**$ 12,739**	$ 13,721
Short-term investments	**89,259**	49,084
Accounts and other receivables	**333**	238
Prepaid and other current assets	**1,222**	1,411
Total current assets	**103,553**	64,454
Long-term investments	**10,981**	—
Property and equipment, net	**1,395**	1,402
Goodwill	**16,659**	16,659
Other assets	**799**	750
Total assets	**$ 133,387**	$ 83,265
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current:		
Accounts payable	**$ 619**	$ 824
Accrued and other liabilities	**5,452**	3,323
Accrued compensation and related liabilities	**2,269**	4,274
Restricted share unit liability	**393**	352
Total current liabilities	**8,733**	8,773
Other liabilities	**8**	105
Class UA preferred stock, 12,500 shares authorized, 12,500 shares issued and outstanding	**30**	30
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized as of September 30, 2017 and December 31, 2016; Series A Convertible Preferred Stock – 2,500 shares and 10,000 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively; Series B Convertible Preferred Stock – 5,333 shares issued and outstanding as of September 30, 2017 and December 31, 2016; Series C Convertible Preferred Stock – 7,500 shares issued and outstanding as of September 30, 2017 and December 31, 2016; Series D Convertible Preferred Stock – 17,250 shares issued and outstanding as of September 30, 2017 and December 31, 2016; Series E Convertible Preferred Stock – 1,818 shares and zero shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	**—**	—
Common stock, $0.0001 par value; 130,000,000 shares and 66,666,667 shares authorized as of September 30, 2017 and December 31, 2016, respectively; 50,560,320 shares and 22,562,640 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively	**353,852**	353,849
Additional paid-in capital	**388,362**	297,922
Accumulated deficit	**(612,506)**	(572,334)
Accumulated other comprehensive loss	**(5,092)**	(5,080)
Total stockholders' equity	**124,616**	74,357
Total liabilities and stockholders' equity	**$ 133,387**	$ 83,265

See accompanying notes to the condensed consolidated financial statements

CASCADIAN THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2017	**2016**	**2017**	**2016**
	(Unaudited)			
Operating expenses				
Research and development	**$ 10,910**	$ 7,281	**$ 31,011**	$ 19,998
General and administrative	**3,448**	3,511	**9,930**	14,509
Intangible asset impairment	**—**	—	**—**	19,738
Total operating expenses	**14,358**	10,792	**40,941**	54,245
Loss from operations	**(14,358)**	(10,792)	**(40,941)**	(54,245)
Other income				
Investment and other income, net	**297**	19	**769**	144
Total other income, net	**297**	19	**769**	144
Loss before income taxes	**(14,061)**	(10,773)	**(40,172)**	(54,101)
Income tax benefit	**—**	—	**—**	(6,908)
Net loss	**$ (14,061)**	$ (10,773)	**$ (40,172)**	$ (47,193)
Deemed dividend related to beneficial conversion feature on convertible preferred stock	**—**	(989)	**(982)**	(2,588)
Net loss attributable to common stockholders	**$ (14,061)**	$ (11,762)	**$ (41,154)**	$ (49,781)
Net loss per share—basic and diluted (1)	**$ (0.28)**	$ (0.52)	**$ (0.87)**	$ (2.74)
Shares used to compute basic and diluted net loss per share (1)	**50,404,201**	22,551,740	**47,089,996**	18,159,603

(1) Basic and diluted net loss per share, and shares to used compute basic and diluted net loss per share for the three and nine months ended September 30, 2016 have been adjusted retroactively to reflect the 1-for-6 reverse stock split.

See accompanying notes to the condensed consolidated financial statements.

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

	Three months ended September 30,		Nine months ended September 30,	
	2017	**2016**	**2017**	**2016**
	(Unaudited)			
Net loss	**$ (14,061)**	$ (10,773)	**$ (40,172)**	$ (47,193)
Other comprehensive income (loss):				
Available-for-sale securities:				
Unrealized gain (loss) during the period, net	**23**	(30)	**(12)**	(1)
Other comprehensive income (loss)	**23**	(30)	**(12)**	(1)
Comprehensive loss	**$ (14,038)**	$ (10,803)	**$ (40,184)**	$ (47,194)

See accompanying notes to the condensed consolidated financial statements

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

	Nine months ended September 30,	
	2017	**2016**
	(Unaudited)	
Cash flows from operating activities		
Net loss	**$ (40,172)**	$ (47,193)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	**538**	483
Amortization of premiums and accretion of discounts on securities	**22**	139
Share-based compensation expense	**2,515**	4,520
Intangible assets impairment	**—**	19,738
Income tax benefit	**—**	(6,908)
Other	**5**	65
Net change in assets and liabilities:		
Accounts and other receivable	**(95)**	(40)
Prepaid expenses and other current assets	**189**	250
Other long-term assets	**(49)**	(395)
Accounts payable	**(205)**	302
Accrued and other liabilities	**2,129**	(27)
Accrued compensation and related liabilities	**(2,005)**	1,638
Other long-term liabilities	**(97)**	(608)
Net cash used in operating activities	**(37,225)**	(28,036)
Cash flows from investing activities		
Purchases of investments	**(117,816)**	(74,000)
Redemption of investments	**66,626**	47,284
Purchases of property and equipment, net	**(536)**	(74)
Net cash used in investing activities	**(51,726)**	(26,790)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance cost	**82,432**	29,823
Proceeds from issuance of convertible preferred stock, net of issuance cost	**5,616**	13,458
Proceeds from exercise of stock options	**—**	42
Cash paid upon conversion of restricted share units	**(79)**	(20)
Recovery of related party short-swing profit	**—**	225
Net cash provided by financing activities	**87,969**	43,528
Decrease in cash and cash equivalents	**(982)**	(11,298)
Cash and cash equivalents, beginning of period	**13,721**	27,850
Cash and cash equivalents, end of period	**$ 12,739**	$ 16,552
Supplemental disclosures of non-cash investing and financing activities:		
Accretion on convertible preferred stock associated with beneficial conversion feature	**$ 982**	$ 2,588

See accompanying notes to the condensed consolidated financial statements.

1. DESCRIPTION OF BUSINESS

Cascadian Therapeutics, Inc. (the Company) is a clinical-stage biopharmaceutical company incorporated in the State of Delaware on September 7, 2007 and is listed on the NASDAQ Global Select Market under the ticker symbol "CASC." The Company is focused primarily on the development of targeted therapeutic products for the treatment of cancer. The Company's goal is to develop and commercialize compounds that have the potential to improve the lives and outcomes of cancer patients. The Company's operations are not subject to any seasonality or cyclicality factors.

2. BASIS OF PRESENTATION

The accompanying unaudited condensed consolidated financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP) for interim financial statements. The accounting principles and methods of computation adopted in these condensed consolidated financial statements are the same as those of the audited consolidated financial statements contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 filed with the Securities Exchange Commission (the SEC) on March 9, 2017.

Omitted from these statements are certain information and note disclosures normally included in the audited consolidated financial statements prepared in accordance with U.S. GAAP. The Company believes all adjustments necessary for a fair statement of the results for the periods presented have been made, and such adjustments consist only of those considered normal and recurring in nature. The financial results for the three and nine months ended September 30, 2017 are not necessarily indicative of financial results for the full year. The condensed consolidated balance sheet as of December 31, 2016 was derived from the audited financial statements at that date. The unaudited condensed consolidated financial statements and notes presented should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2016 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 9, 2017.

Reverse Stock Split

On November 29, 2016, the Company effected a one-for-six reverse stock split of its outstanding common stock. Each six outstanding shares of the Company's common stock were combined into one outstanding share of common stock. All per share and share amounts for all periods presented have been adjusted retrospectively to reflect the 1-for-6 reverse stock split.

Accumulated Other Comprehensive Income (Loss)

Comprehensive income or loss is comprised of net income or loss and other comprehensive income or loss. Other comprehensive income or loss includes unrealized gains and losses on the Company's available-for-sale investments. In addition to unrealized gains and losses on investments, accumulated other comprehensive income or loss consists of foreign currency translation adjustments which arose from the conversion of the Canadian dollar functional currency consolidated financial statements to the U.S. dollar reporting currency consolidated financial statements prior to January 1, 2008. Should the Company liquidate or substantially liquidate its investments in its foreign subsidiaries, the Company would be required to recognize the related cumulative translation adjustments pertaining to the liquidated or substantially liquidated subsidiaries, as a charge to earnings in the Company's condensed consolidated statements of operations and comprehensive loss.

There were no reclassifications out of accumulated other comprehensive loss during the three and nine months ended September 30, 2017. The tables below show the changes in accumulated balances of each component of accumulated other comprehensive loss for the three and nine months ended September 30, 2017 and September 30, 2016:

	Three months ended September 30, 2017		
	Net unrealized gains/(losses) on Available-for-sale Securities	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
		(In thousands)	
Balance at June 30, 2017	$ (49)	$ (5,066)	$ (5,115)
Current period other comprehensive income (loss)	23	—	23
Balance at September 30, 2017	$ (26)	$ (5,066)	$ (5,092)

	Three months ended September 30, 2016		
	Net unrealized gains/(losses) on Available-for-sale Securities	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
		(In thousands)	
Balance at June 30, 2016	$ 31	$ (5,066)	$ (5,035)
Current period other comprehensive loss	(30)	—	(30)
Balance at September 30, 2016	$ 1	$ (5,066)	$ (5,065)

	Nine months ended September 30, 2017		
	Net unrealized gains/(losses) on Available-for-sale Securities	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
		(In thousands)	
Balance at December 31, 2016	$ (14)	$ (5,066)	$ (5,080)
Current period other comprehensive income (loss)	(12)	—	(12)
Balance at September 30, 2017	$ (26)	$ (5,066)	$ (5,092)

	Nine months ended September 30, 2016		
	Net unrealized gains/(losses) on Available-for-sale Securities	Foreign Currency Translation Adjustment	Accumulated Other Comprehensive Loss
		(In thousands)	
Balance at December 31, 2015	$ 2	$ (5,066)	$ (5,064)
Current period other comprehensive income (loss)	(1)	—	(1)
Balance at September 30, 2016	$ 1	$ (5,066)	$ (5,065)

3. RECENT ACCOUNTING PRONOUNCEMENTS

In January 2017, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2017-04, Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. This standard simplifies the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test which previously required measurement of any goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. Instead, under this update, the impairment charge will be measured based on the excess of a reporting unit's carrying value over its fair value. The standard will be applied prospectively and is effective for a public business entity that is an SEC filer for its annual and interim impairment tests performed in periods beginning after December 15, 2019. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. The Company is currently evaluating any impact this standard may have on its consolidated financial position and results of operations.

In March 2016, FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, Compensation – Stock Compensation. This standard changes how companies account for certain aspects of share-based payments to employees including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This standard is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those years. The Company adopted this standard as of January 1, 2017. Because the Company has incurred net losses since its inception and maintains a full valuation allowance on its net deferred tax assets, the adoption of this standard did not have a material impact on the Company's financial condition, results of operations and cash flows, or financial statement disclosures.

In August 2015, FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606)—Deferral of the Effective Date, which defers by one year the effective date of ASU 2014-09, Revenue from Contracts with Customers. For public entities, the standard is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Early adoption is permitted as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. As the Company does not currently have any revenue arrangements in the scope of the new revenue standard, it does not expect the adoption of this standard to have a material effect on its financial position or results of operations. However, if the Company does enter into license, collaboration or other revenue arrangements during 2017, there may be material differences in the accounting treatment under the current guidance and the new revenue standard as of the adoption date, January 1, 2018.

4. FAIR VALUE MEASUREMENTS

The Company measures certain financial assets and liabilities at fair value in accordance with a hierarchy which requires an entity to maximize the use of observable inputs which reflect market data obtained from independent sources and minimize the use of unobservable inputs which reflect the Company's market assumptions when measuring fair value. There are three levels of inputs that may be used to measure fair value:

- Level 1—quoted prices in active markets for identical assets or liabilities;
- Level 2—observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3—unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company's financial assets and liabilities measured at fair value consisted of the following as of September 30, 2017 and December 31, 2016:

	September 30, 2017				**December 31, 2016**			
	Level 1	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
				(In thousands)				
Financial assets:								
Money market funds	**$ 5,271**	**$ —**	**$ —**	**$ 5,271**	$ 6,559	$ —	$ —	$ 6,559
Debt securities of U.S. government agencies	**—**	**66,508**	**—**	**66,508**	—	38,378	—	38,378
Corporate bonds	**—**	**33,732**	**—**	**33,732**	—	10,706	—	10,706
	$ 5,271	**$ 100,240**	**$ —**	**$ 105,511**	$ 6,559	$ 49,084	$ —	$ 55,643
Financial liabilities:								
Restricted share units	**$ 393**	**$ —**	**$ —**	**$ 393**	$ 352	$ —	$ —	$ 352

If quoted market prices in active markets for identical assets are not available to determine fair value, then the Company uses quoted prices of similar instruments and other significant inputs derived from observable market data obtained from third-party data providers. These investments are included in Level 2 and consist of debt securities of U.S government agencies and corporate bonds. There were no transfers between Levels 1 and 2 during the three- and nine-month period ended September 30, 2017.

5. FINANCIAL INSTRUMENTS

Financial instruments consist of cash and cash equivalents, investments and accounts and other receivables that will result in future cash receipts, as well as accounts payable, accrued and other liabilities, restricted share unit liabilities, and Class UA preferred stock that may require future cash outlays.

Investments

Investments are classified as available-for-sale securities and are carried at fair value with unrealized temporary holding gains and losses excluded from net income or loss and reported in other comprehensive income or loss and as a net amount in accumulated other comprehensive income or loss until realized. Available-for-sale securities are written down to fair value through income whenever it is necessary to reflect other-than-temporary impairments. The Company determined that the unrealized losses on its marketable securities as of September 30, 2017 were temporary in nature, and the Company currently does not intend to sell these securities before recovery of their amortized cost basis. All short-term investments are limited to a final maturity of less than one year from the reporting date. The Company's long-term investments are investments with maturities exceeding 12 months from the reporting date. The Company is exposed to credit risk on its cash equivalents, short-term investments and long-term investments in the event of non-performance by counterparties, but does not anticipate such non-performance and mitigates exposure to concentration of credit risk through the nature of its portfolio holdings. If a security falls out of compliance with the Company's investment policy, it may be necessary to sell the security before its maturity date in order to bring the investment portfolio back into compliance. The cost basis of any securities sold is determined by specific identification. The fair value of available-for-sale securities is based on prices obtained from third-party pricing services. The Company reviews the pricing methodology used by the third-party pricing services including the manner employed to collect market information. On a periodic basis, the Company also performs review and validation procedures on the pricing information received from the third-party pricing services. These procedures help ensure that the fair value information used by the Company is determined in accordance with applicable accounting guidance. The amortized cost, unrealized gain or losses and fair value of the Company's cash, cash equivalents and investments for the periods presented are summarized below:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
		(In thousands)		
As of September 30, 2017				
Cash	**$ 7,468**	**$ —**	**$ —**	**$ 7,468**
Money market funds	**5,271**	**—**	**—**	**5,271**
Debt securities of U.S. government agencies	**66,535**	**1**	**(28)**	**66,508**
Corporate bonds	**33,731**	**6**	**(5)**	**33,732**
Total	**$ 113,005**	**$ 7**	**$ (33)**	**$ 112,979**
As of December 31, 2016				
Cash	$ 7,162	$ —	$ —	$ 7,162
Money market funds	6,559	—	—	6,559
Debt securities of U.S. government agencies	38,387	1	(10)	38,378
Corporate bonds	10,711	—	(5)	10,706
Total	$ 62,819	$ 1	$ (15)	$ 62,805

The following table summarizes the aggregate related fair value of investments with unrealized losses by investment category:

	As of September 30, 2017		As of December 31, 2016	
	Fair Value	Gross Unrealized Losses	Fair Value	Gross Unrealized Losses
		(In thousands)		
Debt securities of U.S. government agencies	**$ 60,522**	**$ (28)**	$ 31,990	$ (10)
Corporate bonds	**13,766**	**(5)**	8,955	(5)
Total	**$ 74,288**	**$ (33)**	$ 40,945	$ (15)

The following table summarizes the Company's available-for-sale securities by contractual maturity:

	As of September 30, 2017		As of December 31, 2016	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
		(In thousands)		
Less than one year	**$ 94,549**	**$ 94,530**	$ 55,657	$ 55,643
Greater than one year but less than five years	**10,988**	**10,981**	—	—
Total	**$ 105,537**	**$ 105,511**	$ 55,657	$ 55,643

Accounts and Other Receivables, Accounts Payable and Accrued and Other Liabilities

The carrying amounts of accounts and other receivables, accounts payable and accrued and other liabilities approximate their fair values due to the short-term nature of these financial instruments.

Class UA Preferred Stock

The fair value of class UA preferred stock is assumed to be equal to its carrying value as the amounts that will be paid and the timing of the payments

cannot be determined with any certainty.

Limitations

Fair value estimates are made at a specific point in time, based on relevant market information and information about the financial instrument. These estimates are subjective in nature and involve uncertainties and matters of significant judgment; therefore, they cannot be determined with precision. Changes in assumptions could significantly affect the estimates.

6. INTANGIBLE ASSET IMPAIRMENT

On May 5, 2016, the Company entered into an agreement with STC.UNM to mutually terminate the license agreement relating to protocell technology. As a result of the termination and the Company's intent to no longer develop, license or commercialize the protocell technology, the indefinite-lived intangible assets acquired in the 2014 acquisition of Alpine Biosciences, Inc. (Alpine) were considered impaired. Accordingly, $19.7 million was fully written-off and recorded as intangible asset impairment in the Company's condensed consolidated statements of operations for the three and nine months ended September 30, 2016. The indefinite-lived intangible assets represented the value assigned to in-process research and development when the Company acquired the protocell technology. Additionally, as a result of the impairment, the deferred tax liability, which solely relates to the indefinite-lived intangible assets was reversed, resulting in a federal tax benefit of $6.9 million during the nine months ended September 30, 2016. See "Note 13 — Income Tax" of the unaudited financial statements included in this report for additional information. The impairment charge did not result in any significant cash expenditures or otherwise impact the Company's liquidity or cash. No impairment charges were recorded in the Company's condensed consolidated statements of operations during the three and nine months ended September 30, 2017.

7. NET LOSS PER SHARE ATTRIBUTABLE TO COMMON STOCKHOLDERS

Basic net loss per share is calculated by dividing net loss attributable to common stockholders, which may include a deemed dividend from the amortization of a beneficial conversion feature, by the weighted average number of shares outstanding for the period. Diluted net loss per share is calculated by adjusting the numerator and denominator of the basic net loss per share calculation for the effects of all potentially dilutive common shares. Potential dilutive shares of the Company's common stock include stock options, restricted share units, warrants, Series A, B, C, D and E convertible preferred stock and shares granted under the 2010 Employee Stock Purchase Plan (ESPP). Furthermore, adjustments to the denominator are required to reflect the addition of the related dilutive shares. Shares used to calculate basic and dilutive net loss per share for the three and nine months ended September 30, 2017, were the same, since all potentially dilutive shares were anti-dilutive.

The following table presents the number of shares that were excluded from the number of shares used to calculate diluted net loss per share:

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
	2017	2016	**2017**	2016
Director and employee stock options	**3,248,853**	1,804,159	**3,248,853**	1,804,159
Warrants	**841,449**	841,449	**841,449**	841,449
Convertible preferred stock (as converted to common stock):				
Series A	**416,673**	1,666,697	**416,673**	1,666,697
Series B	**888,851**	888,851	**888,851**	888,851
Series C	**1,250,022**	1,250,022	**1,250,022**	1,250,022
Series D	**2,875,055**	2,875,055	**2,875,055**	2,875,055
Series E	**1,818,000**	—	**1,818,000**	—
Employee restricted share units	**317,600**	—	**317,600**	—
Non-employee director restricted share units	**95,999**	81,612	**95,999**	81,612
Employee stock purchase plan	**17,641**	6,192	**17,641**	6,192

8. EQUITY

Increase in Authorized Common Stock

On June 8, 2017, the stockholders of the Company approved an amendment to the Company's certificate of incorporation to increase the number of the Company's authorized shares of common stock from 66,666,667 to 130,000,000. The Company filed the Certificate of Amendment to the Amended and Restated Certificate of Incorporation with the Delaware Secretary of State to effect such amendment.

January 2017 Financing

On January 27, 2017, the Company closed an underwritten offering for aggregate gross proceeds of $94.0 million, which included both common stock and convertible preferred stock. Aggregate net proceeds from the January 2017 offerings, after underwriting discounts, commissions and other expenses of $6.0 million, were approximately $88.0 million.

Common Stock

On January 27, 2017, the Company closed an underwritten offering of 26,659,300 shares of its common stock at a price to the public of $3.30 per share, for gross proceeds of approximately $88.0 million. The shares included 3,477,300 shares of common stock sold pursuant to the over-allotment option granted by the Company to the underwriters, which option was exercised in full.

Series E Convertible Preferred Stock

In addition, on January 27, 2017, the Company closed an underwritten offering of 1,818 shares of its Series E convertible preferred stock at a price to the public of $3,300 per share, for gross proceeds of approximately $6.0 million. The Company designated 1,818 shares of its authorized and unissued preferred stock as Series E convertible preferred stock and filed a Certificate of Designation of Preferences, Rights and Limitations of Series E Convertible Preferred Stock with the Delaware Secretary of State.

Each share of Series E Convertible Preferred Stock is convertible into 1,000 shares of the Company's Common Stock at any time at the holder's option. The holder, however, will be prohibited from converting Series E Convertible Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 19.99% of the shares of the Company's Common Stock then issued and outstanding, which percentage may change at the holders' election to any other number less than or equal to 19.99% upon 61 days' notice to the Company. In the event of the Company's liquidation, dissolution, or winding up, holders of Series E Convertible Preferred Stock will receive a payment equal to $0.0001 per share of Series E Convertible Preferred Stock before any proceeds are distributed to the holders of common stock, after any proceeds are distributed to the holder of the Company's Class UA Preferred Stock and on parity with any distributions to the holders of the Company's Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock and Series D Convertible Preferred Stock. Shares of Series E Convertible Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series E Convertible Preferred Stock will be required to amend the terms of the Series E Convertible Preferred Stock. Shares of Series E Convertible Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank:

- senior to all common stock;
- senior to any class or series of capital stock created that specifically ranks by its terms junior to the Series E convertible preferred stock;
- on parity with the Company's Series A convertible preferred stock, Series B Convertible Preferred Stock, Series C convertible preferred stock and Series D convertible preferred stock, and any class or series of capital stock created that specifically ranks by its terms on parity with the Series E convertible preferred stock; and
- junior to the Company's Class UA preferred stock and any class or series of capital stock created that specifically ranks by its terms senior to the Series E convertible preferred stock;

in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up, whether voluntarily or involuntarily.

Beneficial Conversion Feature

A beneficial conversion feature exists when the effective conversion price of a convertible security is less than the market price per share on the commitment date, creating a discount. The value of the discount is determined by the difference between the market price and the conversion price multiplied by the potential conversion shares purchased. The discount is recognized as a non-cash deemed dividend from the date of issuance to the earliest conversion date.

The Company recognized a beneficial conversion feature as a non-cash dividend in the amount of $1.0 million, calculated as the number of potential conversion shares multiplied by the excess of the market price of its common stock over the price per conversion share of the Series E convertible preferred stock on the commitment date. The non-cash deemed dividend of $1.0 million was recorded in additional paid-in capital as a deemed dividend on the Series E convertible preferred stock, and was used in determining the net loss applicable to common stockholders in the condensed consolidated statement of operations for the nine months ended September 30, 2017.

June 2016 Financing

On June 28, 2016, the Company closed an underwritten offering for aggregate gross proceeds of $46.0 million, which included both common stock and convertible preferred stock. Aggregate net proceeds from the June 2016 offerings, after underwriting discounts, commissions and other expenses of $2.7 million, were approximately $43.3 million.

Common Stock

On June 28, 2016, the Company closed an underwritten public offering of 6,708,333 shares of its common stock at a price to the public of $4.80 per share for gross proceeds of $32.2 million. The shares included 875,000 shares of common stock sold pursuant to the option granted by the Company to the underwriters to purchase additional shares, which was exercised in full.

Series D Convertible Preferred Stock

In addition, on June 28, 2016, the Company closed a registered direct offering of 17,250 shares of its Series D Convertible Preferred Stock at a price of $800.00 per share directly to affiliates of BVF Partners L.P. (BVF), which are existing stockholders and affiliates of a former member of the board of directors, for gross proceeds of $13.8 million. The Company designated 17,250 shares of its authorized and unissued preferred stock as Series D convertible preferred stock and filed a Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock with the Delaware Secretary of State.

Each share of Series D Convertible Preferred Stock is convertible into 166.67 shares of the Company's Common Stock at any time at the holder's option. The holder, however, will be prohibited from converting Series D Convertible Preferred Stock into shares of common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 19.99% of the shares of the Company's Common Stock then issued and outstanding, which percentage may change at the holders' election to any other number less than or equal to 19.99% upon 61 days' notice to the Company. In the event of the Company's liquidation, dissolution, or winding up, holders of Series D Convertible Preferred Stock will receive a payment equal to $0.0001 per share of Series D Convertible Preferred Stock before any proceeds are distributed to the holders of common stock, after any proceeds are distributed to the holder of the Company's Class UA Preferred Stock and on parity with any distributions to the holders of the Company's Series A Convertible Preferred Stock, Series B Convertible Preferred Stock, Series C Convertible Preferred Stock and Series E Convertible Preferred Stock. Shares of Series D Convertible Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series D Convertible Preferred Stock will be required to amend the terms of the Series D Convertible Preferred Stock. Shares of Series D Convertible Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by the Company's board of directors, and will rank:

- senior to all common stock;
- senior to any class or series of capital stock created that specifically ranks by its terms junior to the Series D convertible preferred stock;
- on parity with the Company's Series A convertible preferred stock, Series B Convertible Preferred Stock, Series C convertible preferred stock and Series E convertible preferred stock, and any class or series of capital stock created that specifically ranks by its terms on parity with the Series D convertible preferred stock; and
- junior to the Company's Class UA preferred stock and any class or series of capital stock created that specifically ranks by its terms senior to the Series D convertible preferred stock;

in each case, as to distributions of assets upon the Company's liquidation, dissolution or winding up, whether voluntarily or involuntarily.

Beneficial Conversion Feature

The Company recognized a beneficial conversion feature in the amount of $2.6 million, calculated as the number of potential conversion shares multiplied by the excess of the market price of its common stock over the price per conversion share of the Series D convertible preferred stock on the commitment date. The Company immediately accreted $1.6 million of the $2.6 million beneficial conversion feature, representing approximately 60% of the Series D convertible preferred stock that could be converted at that time, upon issuance. The Company accreted the remaining $1.0 million beneficial conversion feature, representing 40% of the Series D convertible preferred stock that could not be converted upon issuance due to certain contractual limitations, from the issuance date to the earliest conversion date, which fell within the third quarter of 2016. The non-cash dividend of $1.0 million and $2.6 million was recorded in additional paid-in capital and as a deemed dividend on the Series D convertible preferred stock, and was used in determining the net loss applicable to common stockholders in the consolidated statement of operations for the three and nine months ended September 30, 2016, respectively.

"At-the-Market" Equity Offering Program

On June 2, 2016, the Company entered into a Sales Agreement (the Sales Agreement) with Cowen and Company, LLC (Cowen) to sell shares of the Company's common stock, par value $0.0001 per share, having aggregate sales proceeds of up to $50,000,000, from time to time, through an "at the market" equity offering program under which Cowen will act as sales agent. The Company terminated the Sales Agreement effective as of the close of business on January 23, 2017. No shares were sold under the Sales Agreement.

Conversion of Series A Convertible Preferred Stock into Common Stock

During the three and nine months ended September 30, 2017, 7,500 shares of Series A convertible preferred stock were converted into 1,250,024 shares of the Company's common stock. As of September 30, 2017, the Company had 2,500 shares of Series A convertible preferred stock issued and outstanding.

9. WARRANTS

As of September 30, 2017, and December 31, 2016, equity-classified warrants to purchase a total of 841,449 shares of the Company's common stock were outstanding. No warrants were exercised or expired during the three and nine months ended September 30, 2017 and September 30, 2016.

In June 2013, the Company issued equity-classified warrants to purchase 833,333 shares of common stock at an exercise price of $30.00 per share in connection with a registered direct offering to Biotechnology Value Fund, L.P. and other affiliates of BVF. The warrants expire on December 5, 2018.

In February 2011, the Company issued equity-classified warrants to purchase 8,116 shares of common stock at an exercise price of $18.48 per share in connection with a loan and security agreement entered into with General Electric Capital Corporation, now Capital One National Association. The warrants expire on February 8, 2018.

10. SHARE-BASED COMPENSATION

The Company uses the Black-Scholes option pricing model to value the options at each grant date, using the following weighted average assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	**2017**	2016
Expected dividend rate	**0.00%**	0.00%	**0.00%**	0.00%
Expected volatility	**75.96%**	74.05%	**76.47%**	74.67%
Risk-free interest rate	**1.90%**	1.34%	**1.94%**	1.42%
Expected life of options (in years)	**5.69**	6.20	**5.69**	6.22

The expected life represents the period that the Company's stock options are expected to be outstanding and is based on historical data. The expected volatility is based on the historical volatility of the Company's common stock for a period equal to the stock option's expected life. The risk-free interest rate is based on the yield at the time of grant of a U.S. Treasury security with an expected term equivalent to the expected term of the option. The Company does not expect to pay dividends on its common stock. The amounts estimated according to the Black-Scholes option pricing model may not be indicative of the actual values realized upon the exercise of these options by the holders.

The Company recognizes share-based compensation expense net of estimated forfeitures. The forfeiture rate is estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. The Company's estimated forfeiture rate at the time of grant is based on its historical experience.

Share-based compensation expense under the 2016 Equity Incentive Plan (2016 EIP), the Amended and Restated Share Option Plan (the Option Plan), and for an inducement grant, was $0.7 million for each of the three months ended September 30, 2017 and September 30, 2016. Share-based compensation expense was $2.4 million and $4.6 million for the nine months ended September 30, 2017 and September 30, 2016, respectively. The Share-based compensation expense during the nine months ended September 30, 2016 included the acceleration of share-based compensation expense in connection with management changes in the first quarter of 2016.

2016 Equity Incentive Plan

On June 23, 2016, the Company's stockholders approved the 2016 EIP. As of that date, the Company ceased granting options under its Option Plan, ceased granting restricted shares units under its Amended and Restated RSU Plan (the RSU Plan) and transferred the remaining shares available for issuance under the Option Plan and the RSU Plan to the 2016 EIP. As of the effective date of the 2016 EIP, 1,200,905 shares of common stock were reserved for issuance under the 2016 EIP, consisting of 1,050,000 shares available for awards under the 2016 EIP plus 82,884 and 68,021 shares of common stock previously reserved but unissued under the Option Plan and the RSU Plan, respectively, that were available for issuance under the 2016 EIP on the effective date of the 2016 EIP. On June 8, 2017, the Company's stockholders approved an amendment to the 2016 EIP to increase the total shares of common stock available for issuance under the 2016 EIP from 1,200,905 shares to 7,900,905 shares.

All grants under the 2016 EIP may have a term up to ten years from the date of grant. Vesting schedules are determined by the compensation committee of the board of directors or its designee when each award is granted. Upon vesting of RSUs granted to employees, a portion of the RSUs will be settled in cash equivalent to the employee's minimum required withholding tax on the value of the vested RSUs. The Company measures and recognizes compensation expense for equity-classified restricted stock units (RSUs), and stock options granted to our employees based on the fair value of the awards on the date of grant. The fair value of each RSU was determined to be the closing trading price of the Company's common shares on the date of grant as quoted in NASDAQ Global Market. The fair value of stock options is estimated at the date of grant using the Black-Scholes option pricing model. Share-based compensation expense for equity-classified RSUs, and stock options is recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective award. RSU grants made to its non-employee directors are classified as liabilities. Share-based compensation expense for liability-classified RSUs are re-measured at each reporting date until settlement of the award.

During the three months ended September 30, 2017 and September 30, 2016, the Company did not grant RSUs to its non-employee directors. During the nine months ended September 30, 2017 and September 30, 2016, the Company granted 95,999 RSUs with a fair value of approximately $350,000 and 54,348 RSUs with a fair value of $300,000 to its non-employee directors, respectively. During the three and nine months ended September 30, 2017, the Company issued zero and 54,348 shares, respectively, upon conversion of RSUs under the 2016 EIP. During the three months ended September 30, 2017, the Company granted 778,380 stock options and 180,560 RSUs to its employees under the 2016 EIP. During the nine months ended September 30, 2017, the Company granted 1,502,923 stock options and 324,700 RSUs to its employees under the 2016 EIP. During the three and nine months ended September 30, 2016, the Company granted 23,469 stock options under the 2016 EIP. No stock options were exercised under the 2016 EIP during the three and nine months ended September 30, 2017 and September 30, 2016. As of September 30, 2017, there were 5,738,006 shares of common stock available for future grant under the 2016 EIP.

Option Plan

Under the Option Plan, a maximum fixed reloading percentage of 10% of the issued and outstanding common stock of the Company could be granted to employees, directors and service providers. On June 23, 2016, the stockholders approved the 2016 EIP and the Company ceased granting options under the Option Plan. Options granted under the Option Plan prior to January 2010 began vesting after one year from the date of grant, are exercisable in equal amounts over four years on the anniversary date of the grant, and expire eight years following the date of grant. Options granted to employees under the Option Plan after January 2010 vest 25% on the first anniversary of the vesting commencement date, with the balance vesting in monthly increments for 36 months following the first anniversary of grant, and expire eight years following the date of grant. Due to the adoption of the 2016 EIP on June 23, 2016, all shares remaining for future grant under the Option Plan were transferred to the 2016 EIP plan leaving no shares of common stock available for future grant under the Option Plan.

During the three and nine months ended September 30, 2016, the Company granted zero and 313,040 stock options under the Option Plan. No stock options were exercised during each of the three and nine months ended September 30, 2017 and September 30, 2016.

Inducement Grant

On April 4, 2016, the Company made an inducement stock option grant (Inducement Grant) of 474,810 options. Options granted under the Inducement Grant vest 25% on the first anniversary of the vesting commencement date, with the balance vesting in monthly increments for 36 months following the first anniversary of grant, and expire ten years following the date of grant. No stock options were exercised under the inducement grant during the three and nine months ended September 30, 2017.

Restricted Share Unit Plan

The RSU Plan was established in 2005 for non-employee directors. On June 23, 2016, the stockholders approved the 2016 EIP and the Company ceased granting RSUs under the RSU Plan.

The RSU Plan provided for grants to be made from time to time by the board of directors or a committee thereof. RSU grants to non-employee directors are classified as liabilities. The fair value of each RSU was determined to be the closing trading price of the Company's common shares on the date of grant as quoted in NASDAQ Global Market. Each RSU granted was made in accordance with the RSU Plan and terms specific to that grant. Outstanding RSUs under the RSU Plan have a vesting term of one to two years. Approximately 75% of each RSU represents a contingent right to receive approximately 0.75 of a share of the Company's common stock upon vesting and approximately 25% represents a contingent right to receive cash, equivalent to the value of 0.25 of a share, upon vesting without any further consideration payable to the Company in respect thereof. For the contingent right to receive cash, the Company is required to deliver an amount in cash equal to the fair market value of these shares on the vesting date to facilitate the satisfaction of the non-employee directors' U.S. federal income tax obligation with respect to the vested RSUs. The outstanding RSU awards are required to be re-measured at each reporting date until settlement of the award, and changes in valuation are recorded as compensation expense for the period. The fair value of the outstanding RSUs on the reporting date was determined to be the closing trading price of the Company's common shares on that date.

The re-measurement of the outstanding RSUs together with the grant and conversion of the RSUs under the RSU Plan resulted in $2,090 and a reduction of $11,980 in share-based compensation expense recorded in general and administrative expenses in the condensed consolidated statement of operations for the three and nine months ended September 30, 2017, respectively. The re-measurement of the outstanding RSUs together with the grant and conversion of the RSUs resulted in $0.1 million and a reduction of $0.2 million in share-based compensation expense recorded in general and administrative expenses in the condensed consolidated statement of operations for the three and nine months ended September 30, 2016, respectively.

Upon the adoption of the 2016 EIP on June 23, 2016, all shares remaining for future grant under the RSU Plan became available for issuance under the 2016 EIP plan and the Company ceased granting RSUs under the RSU Plan. For the three and nine months ended September 30, 2017, 9,500 and 27,271 shares, respectively, were issued upon conversion of RSUs under the RSU Plan. For the three and nine months ended September 30, 2016, zero and 10,893 shares were issued upon conversion of RSUs under the RSU Plan.

Employee Stock Purchase Plan

The Company adopted an Employee Stock Purchase Plan (ESPP) on June 3, 2010, pursuant to which a total of 150,000 shares of common stock were reserved for sale to employees of the Company. The ESPP is administered by the compensation committee of the board of directors and is open to all eligible employees of the Company. Under the terms of the ESPP, eligible employees may purchase shares of the Company's common stock at six month intervals during 18-month offering periods through periodic payroll deductions, which may not exceed 15% of any employee's compensation and may not exceed a value of $25,000 in any calendar year, at a price not less than the lesser of an amount equal to 85% of the fair market value of the Company's common stock at the beginning of the offering period or an amount equal to 85% of the fair market value of the Company's common stock on each purchase date. The maximum aggregate number of shares that may be purchased by each eligible employee during each offering period is 15,000 shares of the Company's common stock. For the three and nine months ended September 30, 2017, expense related to this plan was $45,284 and $144,246, respectively. For the three and nine months ended September 30, 2016, expense related to this plan was $25,014 and $93,707, respectively. Under the ESPP, the Company did not issue any shares to employees during each of the three-month periods ended September 30, 2017 and September 30, 2016. The Company issued 27,146 shares and 8,261 shares to employees during the nine months ended September 30, 2017 and September 30, 2016, respectively. There were 42,527 shares reserved for future issuances under the ESPP as of September 30, 2017.

11. CONTINGENCIES, COMMITMENTS, AND GUARANTEES

Pursuant to various license agreements, the Company may be obligated to make payments based on the achievement of certain event-based milestones, a percentage of revenues derived from the licensed technology and royalties on net sales. As of September 30, 2017, no payments were obligated as there were no milestones achieved, no technology licensed and the Company had no net sales, as defined in the agreements. As such, the Company is not currently contractually committed to any significant quantifiable payments for licensing fees, royalties or other contingent payments.

On January 9, 2016, the Company adopted a Retention Payment Plan, effective as of January 11, 2016 (Retention Plan), to provide cash retention payments to certain employees in order to induce such employees to remain employed through January 10, 2017 (Retention Date). Any employee who participated in the Retention Plan and (i) remained continuously employed by the Company through the Retention Date or (ii) had been terminated by the Company other than for cause prior to the Retention Date, and (iii) signed a general release of claims was paid a lump-sum cash payment as determined on an individual basis. If such employee's service was terminated for cause or the employee voluntarily resigned prior to the Retention Date, no such payments were to be made. In January 2017, the Company paid $2.5 million related to this plan. There were no expenses related to the Retention Plan recorded under the Retention Plan for the three months ended September 30, 2017. An expense of $0.1 million related to the Retention Plan was recorded in the condensed consolidated statement of operations for the nine months ended September 30, 2017. An expense of $0.5 million and $1.9 million related to the Retention Plan was recorded in the condensed consolidated statement of operations for the three and nine months ended September 30, 2016, respectively. As of September 30, 2017, there were no liabilities recorded under the Retention Plan, since all obligations under the Retention Plan were paid in full.

In the normal course of operations, the Company indemnifies counterparties in transactions such as purchase and sale contracts for assets or shares, manufacturing and other service agreements, license agreements, director/officer contracts and leasing transactions. These indemnification agreements may require the Company to compensate the counterparties for costs incurred to third parties as a result of various events, including changes in (or in the interpretation of) laws and regulations, the Company's breach of contract or negligence, environmental liabilities, or as a result of litigation claims or statutory sanctions that may be suffered by the counterparties as a consequence of the transaction. The terms of these indemnification agreements vary based upon the contract, the nature of which prevents the Company from making a reasonable estimate of the maximum potential amount that could be required to pay to counterparties. Historically, the Company has not made any significant payments under such indemnification agreements and no amounts have been accrued in the accompanying condensed consolidated financial statements with respect to these indemnification agreements.

12. COLLABORATIVE AND LICENSE AGREEMENTS

Array BioPharma, Inc.

On December 11, 2014, the Company entered into a License Agreement (the License Agreement) with Array BioPharma Inc. (Array). Pursuant to the License Agreement, Array granted the Company an exclusive license to develop, manufacture and commercialize tucatinib (previously known as ONT-380), an orally active, reversible and selective small-molecule HER2 inhibitor.

Under the terms of the License Agreement, the Company paid Array an upfront fee of $20 million, which was recorded as part of research and development expense upon initiation of the exclusive license agreement. In addition, if the Company sublicenses rights to tucatinib to a third party, the Company will pay Array a percentage of any sublicense payments it receives, with the percentage varying according to the stage of development of tucatinib at the time of the sublicense. If the Company is acquired within three years of the effective date of the License Agreement, and tucatinib has not been sublicensed to another entity prior to such acquisition, then the acquirer will be required to make certain milestone payments of up to $280 million to Array, which are primarily based on potential tucatinib sales. Array is also entitled to receive up to a double-digit royalty based on net sales of tucatinib.

The License Agreement will expire on a country-by-country basis 10 years following the first commercial sale of the product in each respective country, but may be terminated earlier by either party upon material breach of the License Agreement by the other party or the other party's insolvency, or by the Company on 180 days' notice to Array. The Company and Array have also agreed to indemnify the other party for certain of their respective warranties and obligations under the License Agreement.

STC.UNM

Effective June 30, 2014, Alpine Biosciences, Inc, (Alpine) entered into an exclusive license agreement with STC.UNM, by assignment from The Regents of the University of New Mexico, to license the rights to use certain technology relating to protocells, a mesoporous silica nanoparticle delivery platform. The Company subsequently acquired Alpine in August 2014. Under the terms of the license agreement, the Company, as successor to Alpine, had the right to conduct research, clinical development and commercialize all inventions and products that are developed from the platform technology in certain fields of use as described in the license agreement.

On May 5, 2016, the Company entered into an agreement with STC.UNM to terminate the license agreement relating to protocell technology. The agreement provided for a mutual release of claims and payment of a termination and license fee totaling $325,000. As a result of the termination and the Company's intent to no longer develop, license or commercialize the protocell technology, the indefinite-lived intangible assets acquired in the 2014 acquisition of Alpine were considered impaired. Accordingly, $19.7 million was fully written-off and recorded as intangible asset impairment in the Company's condensed consolidated statements of operations for the nine months ended September 30, 2016. The indefinite-lived intangible assets represent the value assigned to in-process research and development when the Company acquired the protocell technology. The Company also recognized a $6.9 million tax benefit during the nine months ended September 30, 2016, upon the reversal of its deferred tax liability, which solely relates to the indefinite-lived intangible assets. In addition, $1.5 million of previously recorded time-based milestones for license fees associated with the STC.UNM license agreement was reversed from research and development expenses during the nine months ended September 30, 2016. The impairment charge did not result in any significant future cash expenditures, or otherwise impact the Company's liquidity or cash. Please refer to "Note 8 — Collaborative and License Agreements" of the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 9, 2017 for additional information.

Sentinel Oncology Ltd.

In April 2014, the Company entered into an exclusive license and research collaboration agreement with Sentinel Oncology Limited (Sentinel) for the development of novel small molecule Chk1 kinase inhibitors. Under the agreement, the Company has made payments to Sentinel to support their chemistry research. The Company is responsible for preclinical and clinical development, manufacturing and commercialization of any resulting compounds. Sentinel is eligible to receive success-based development and commercial milestone payments up to approximately $90 million based on development and commercialization events, including a $1.0 million milestone for the initiation of GLP toxicology studies and certain payments related to the initiation of certain clinical trials, regulatory approval and first commercial sale. Sentinel is also entitled to a single-digit royalty based on net sales.

13. INCOME TAX

Due to projected and actual losses for the year ended December 31, 2017 and 2016, respectively, and the Company's history of losses, the Company has not recorded an income tax benefit for the three and nine months ended September 30, 2017 and the three months ended September 30, 2016. The Company has recognized a valuation allowance on substantially all its deferred tax assets. The Company's net deferred tax liabilities were recorded in deferred tax liability on the condensed consolidated balance sheets as of September 30, 2017 and December 31, 2016.

During the nine months ended September 30, 2016, the Company recorded an income tax benefit of $6.9 million due to the reversal of its deferred tax liability, which related solely to the impairment of the indefinite-lived intangible asset. For additional information, see "Note 6 — Intangible Asset Impairment" of the unaudited financial statements included in this report. Otherwise, due to projected losses for 2016 and a history of losses, the Company has not recorded an additional income tax benefit for the nine months ended September 30, 2016 and has recognized a valuation allowance on all its deferred tax assets.

14. RELATED PARTY TRANSACTIONS

Certain of the Company's affiliates participated in the Company's recent public underwritten offerings. In January 2017, the Company closed an underwritten offering of 26,659,300 shares of its common stock at a price of $3.30 per share, for gross proceeds of $88.0 million, and 1,818 shares of its Series E convertible preferred stock at a price of $3,300 per share for gross proceeds of $6.0 million. In this offering, affiliates of New Enterprise Associates, a holder of more than 5% of the Company's outstanding common stock, purchased 1,818 shares of the Company's Series E preferred stock for an aggregate purchase price of $6.0 million. In June 2016, the Company closed an underwritten public offering of 6,708,333 shares of our common stock at a price to the public of $4.80 per share, for gross proceeds of $32.2 million, and 17,250 shares of its Series D convertible preferred stock at a price of $800.00 per share for gross proceeds of $13.8 million. In this offering, affiliates of BVF, a holder of more than 5% of the Company's outstanding common stock, purchased 17,250 shares of the Company's Series D preferred stock for an aggregate purchase price of $13.8 million.

In January 2016, the Company appointed Mr. Mark Lampert as a member of the board of directors as a Class I director of the Company. Mr. Lampert is an affiliate of BVF. On January 17, 2017, Mr. Mark Lampert resigned from the board of directors.

15. SUBSEQUENT EVENTS

None.

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

The information in this Item 2—"Management's Discussion and Analysis of Financial Condition and Results of Operations" should be read in conjunction with our condensed consolidated financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements or incorporates by reference forward-looking statements. 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, or in some cases, our partners' future plans, objectives, expectations, intentions and financial performance and the assumptions that underlie these statements. These forward-looking statements include, but are not limited to, statements regarding:

- *the results we anticipate from our pre-clinical development activities and the clinical trials of our product candidates;*
- *our belief that our product candidates could potentially be useful for many different oncology indications that address large markets;*
- *our ability to manage our growth;*
- *the size of the markets for the treatment of conditions our product candidates target;*
- *our ability to acquire or in-license additional product candidates and technologies on commercially reasonable terms, or at all;*
- *our ability to engage clinical trial sites and enroll patients in our pivotal HER2CLIMB study;*
- *our ability to develop and commercialize tucatinib;*
- *our ability to generate future revenue;*
- *financing to support our operations, clinical trials and commercialization of our products;*
- *our ability to adequately protect our proprietary information and technology from competitors and avoid infringement of proprietary information and technology of our competitors;*
- *the possibility that reimbursement programs or government-imposed price restrictions may make our products, if successfully developed and commercialized following regulatory approval, unprofitable;*
- *potential exposure to product liability claims and the impact that successful claims against us will have on our ability to commercialize our product candidates;*
- *our ability to obtain on commercially reasonable terms adequate product liability insurance for our commercialized products;*

- *the possibility that competing products or technologies may make our products, if successfully developed and commercialized following regulatory approval, obsolete;*

- *our ability to succeed in finding and retaining joint venture and collaboration partners to assist us in the successful development, marketing, distribution and commercialization of our product candidates and/or approved products;*

- *our ability to attract and retain highly qualified scientific, clinical, manufacturing, and management personnel;*

- *our ability to identify and capitalize on possible collaboration, strategic partnering, acquisition or divestiture opportunities; and*

- *potential problems with third parties, including suppliers and key personnel, upon whom we are dependent.*

All forward-looking statements are based on information available to us on the date of this quarterly report and we will not update any of the forward-looking statements after the date of this quarterly report, except as required by law. Our actual results could differ materially from those discussed in this quarterly report. The forward-looking statements contained in this quarterly report, and other written and oral forward-looking statements made by us from time to time, 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 quarterly report in Part II, Item 1A—"Risk Factors," and elsewhere in this quarterly report.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of therapeutic products for the treatment of cancer. Our goal is to develop and commercialize novel targeted compounds that have the potential to improve the lives and outcomes of cancer patients. Our lead clinical-stage product candidate is tucatinib, an oral, HER2-selective small molecule tyrosine kinase inhibitor. Our pipeline also includes CASC-578, a Chk1 kinase inhibitor, and CASC-674, an antibody program against an immuno-oncology target known as TIGIT, both of which are currently in preclinical development.

Tucatinib is an investigational orally bioavailable, potent tyrosine kinase inhibitor (TKI) that is highly selective for HER2, also known as ErbB2, a growth factor receptor that is over-expressed in approximately 20% of breast cancers. In addition to breast cancer, HER2 is over-expressed in other malignancies, including subsets of bladder, cervical, colorectal, esophageal, gastric, lung and ovarian cancers. We are currently developing tucatinib for the treatment of HER2-positive (HER2+) metastatic breast cancer. Over-expression of HER2 in breast cancer has been associated historically with increased mortality in early stage disease, decreased time to relapse and increased incidence of metastases. Similarly, the overexpression of HER2 is thought to play an important role in the development and progression of other cancers.

The introduction of HER2-targeted therapies, including antibody-based therapies and small molecule TKIs, has led to improvement in the outcomes of patients with HER2+ cancer. Unlike pan-HER TKIs, tucatinib selectively inhibits HER2 and is at least 1,000-fold more selective for HER2 than the epidermal growth factor receptor (EGFR). This selectivity may improve drug tolerability by reducing the risk of severe diarrhea and skin rash commonly seen with pan-HER TKIs.

We are currently conducting a randomized (2:1), double-blind, controlled pivotal clinical trial, known as HER2CLIMB, comparing tucatinib versus placebo, each in combination with capecitabine (Xeloda®) and trastuzumab (Herceptin®), and without loperamide or budesonide prophylaxis, in patients with locally advanced or metastatic HER2+ breast cancer who have had prior treatment with a taxane, trastuzumab, pertuzumab (Perjeta®) and ado-trastuzumab emtansine or T-DM1 (Kadcyla®) and who may or may not have brain metastases. The primary endpoint is progression-free survival (PFS) based upon independent radiologic review. Patients will also be followed for overall survival, which is a secondary endpoint. Key objectives related to assessing activity in brain metastases include a secondary endpoint of PFS in a subset of patients with brain metastases. HER2CLIMB is currently enrolling patients in the United States, Canada, Western Europe and Australia and is expected to expand into Israel by the end of the year. The HER2CLIMB clinical trial is intended to support a potential new drug application (NDA) submission to the United States Food and Drug Administration (FDA) and a potential Marketing Authorization Application (MAA) to the European Medicines Agency (EMA).

In addition, our two Phase 1b trials of tucatinib, one in combination with T-DM1 and another in combination with capecitabine and/or trastuzumab, are fully enrolled and active patients remain on treatment. Results to date from the Phase 1b trials indicate these drug combinations are well tolerated and may provide clinical activity in heavily pretreated patients with metastatic breast cancer, with and without brain metastases.

In December 2016, we announced updated data from the Phase 1b triplet combination study (tucatinib with capecitabine and trastuzumab). The updated results showed that the combination continued to be well tolerated. Compared to previously reported interim results, the updated PFS increased to 7.8 months and the overall response rate (ORR) increased to 61%. The median duration of response was 10 months. Patients in the Phase 1b triplet combination trial previously received a median of three HER2-targeted agents such as trastuzumab, pertuzumab, lapatinib or T-DM1. These updated results were presented at the 2016 San Antonio Breast Cancer Symposium.

In September 2017, results from the pooled analysis of Phase 1b combination studies showed further support for the potential utility of tucatinib for patients with HER2+ metastatic breast cancer with brain metastases, including untreated or progressive brain metastases after radiation therapy. In addition, data from nonclinical models were presented that support the evaluation of tucatinib in HER2+ gastrointestinal cancers. These results were presented at the European Society for Medical Oncology 2017 Congress.

Tucatinib is also being evaluated in investigator-initiated studies in combination with approved agents. In June 2017, a Phase 2 study called MOUNTAINEER was initiated to evaluate tucatinib in combination with trastuzumab for patients with HER2 amplified metastatic colorectal cancer and recently began enrolling participants in the U.S.

In July 2017, we announced that the EMA confirmed that positive results from HER2CLIMB could serve as a single registrational trial for submission of a MAA to the EMA for potential marketing approval. We had received similar confirmation from the FDA in 2016.

In September 2017, we announced tucatinib was granted orphan drug designation by the FDA for the treatment of HER2+ colorectal cancer and, in June 2017, we announced that tucatinib was granted orphan drug designation by the FDA for the treatment of breast cancer patients with brain metastases.

In June 2016, tucatinib was granted Fast Track designation by the FDA for the treatment of metastatic HER2+ breast cancer. The FDA's Fast Track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

We have an exclusive license agreement with Array BioPharma Inc. for the worldwide rights to develop, manufacture and commercialize tucatinib.

Financial Summary

We have incurred substantial losses since our inception. As of September 30, 2017, our accumulated deficit totaled $612.5 million. We incurred a net loss attributable to common stockholders of $41.2 million for the nine months ended September 30, 2017 compared to a net loss attributable to common stockholders of $49.8 million for the same period in 2016. The decrease in net loss attributable to common stockholders for the nine months ended September 30, 2017 was primarily due to the intangible asset impairment charge of $19.7 million in connection with our termination of the STC.UNM license agreement in 2016. As a result of the termination and our intent to no longer develop, license or commercialize the protocell technology, the $19.7 million in indefinite-lived intangible assets were considered fully impaired and written-off during the nine months ended September 30, 2016. For additional information, please refer to "Note 12 — Collaborative and License Agreements" of the unaudited financial statements included in this report. In addition, the decrease in loss was due to lower general and administrative expenses of $4.6 million primarily due to compensation-related expenses in connection with management changes in the first quarter of 2016 and lower non-cash expense from the deemed dividend related to the beneficial conversion feature on convertible preferred stock, which was $1.0 million for the nine months ended September 30, 2017 compared to $2.6 million for the nine months ended September 30, 2016. The decreases in net loss attributable to common stockholders were partially offset by higher research and development expenses of $11.0 million due to increased enrollment activity related to tucatinib HER2CLIMB clinical trials and a non-cash tax benefit of $6.9 million related to the reversal of our deferred tax liability that was solely due to the indefinite-lived intangible asset that was written off during the nine months ended September 30, 2016. In future periods, we expect to continue to incur substantial net losses as we continue our research and development activities with respect to our product candidates. From inception to date we have funded our operations principally through the sale of our equity securities, cash received through our strategic partners, government grants, debt financings and equipment financings.

Key Financial Metrics

Expenses

Research and Development . Research and development expense consists of costs associated with research activities as well as costs associated with our product development efforts, including costs associated with conducting preclinical studies, clinical development activities and manufacturing costs. These expenses primarily include external research and development expenses incurred pursuant to agreements with third-party manufacturing and contract research and clinical organizations; technology access and licensing fees related to the use of proprietary third-party technologies; and internal expenses associated with employee related costs, including salaries, share-based compensation expense, benefits and related costs; allocated facility overhead which includes depreciation; and third-party consulting and supplier expenses. We recognize research and development expenses, including those paid to third parties, as they are incurred.

General and Administrative . General and administrative expense consists principally of salaries, benefits, share-based compensation expense and related costs for personnel in our executive, business development, finance, accounting, legal, human resources and information technology services functions. Other general and administrative expenses include professional fees for legal, consulting and accounting services, and allocation of our facility costs, which includes depreciation.

Intangible Asset Impairment. On May 5, 2016, we entered into an agreement with STC.UNM to mutually terminate the license agreement relating to the protocell technology. As a result of the termination and our intent to no longer develop, license or commercialize the protocell technology, the indefinite-lived intangible assets acquired in the 2014 acquisition of Alpine, valued at $19.7 million, were considered fully impaired. $19.7 million was written-off and recorded as intangible asset impairment charge in our condensed consolidated statements of operations for the nine months ended September 30, 2016. The indefinite-lived intangible assets represent the value assigned to in-process research and development when we acquired the protocell technology. The impairment charge did not result in any significant cash expenditures, or otherwise impact our liquidity or cash. For more information, see "Note 12 — Collaborative and License Agreements" of the unaudited financial statements included in this report.

Investment and Other Income (Expense) Net . Net investment and other income (expense) consisted of interest and other income on our cash and short-term and long-term investments, debt, foreign exchange gains and losses and other non-operating income (expense). Our investments consist of money market funds, debt securities of U.S. government agencies, highly rated commercial paper, bank notes and corporate bonds.

Income tax (benefit) provision. Due to the $19.7 million impairment of indefinite-lived intangible assets, we reversed our deferred tax liability, which solely relates to the indefinite-lived intangible assets, and recorded a $6.9 million tax benefit in our condensed consolidated statements of operations for the nine months ended September 30, 2016. For more information, see "Note 12 — Collaborative and License Agreements" of the unaudited financial statements included in this report.

Critical Accounting Policies and Significant Judgments and Estimates

We have prepared this Management's Discussion and Analysis of Financial Condition and Results of Operations based on our condensed consolidated financial statements, which have been included elsewhere in this report and which have been prepared in accordance with generally accepted accounting principles in the United States. These accounting principles require us to make estimates and judgments that can affect the reported amounts of assets and liabilities as of the dates of our consolidated financial statements as well as the reported amounts of revenue and expense during the periods presented. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption, there may also be other estimates or assumptions that are reasonable. We believe that the estimates and judgments upon which we rely are reasonable based upon historical experience and information available to us at the time that we make these estimates and judgments. To the extent there are material differences between these estimates and actual results, our consolidated financial statements will be affected. Although we believe that our judgments and estimates are appropriate, actual results may differ from these estimates.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2016 filed with the SEC on March 9, 2017. There have been no material changes in our critical accounting policies and judgments since that date.

Results of Operations for the Three- and Nine- Month Periods Ended September 30, 2017 and September 30, 2016

Overview

The following table sets forth selected consolidated statements of operations data for each of the periods indicated.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In millions)		(In millions)	
Operating expenses	$ (14.4)	$ (10.8)	$ (40.9)	$ (54.2)
Income tax benefit	$ —	$ —	$ —	$ (6.9)
Deemed dividend on convertible preferred stock	$ —	$ (1.0)	$ (1.0)	$ (2.6)
Net loss attributable to common stockholders	$ (14.1)	$ (11.8)	$ (41.2)	$ (49.8)

Operating expenses incurred in the three months ended September 30, 2017 increased by $3.6 million, or 33.3%, compared to the three months ended September 30, 2016. The increase in our operating expenses was due to an increase in research and development expenses of $3.6 million primarily due to greater activity related to the development of our product candidates.

Operating expenses incurred in the nine months ended September 30, 2017 decreased by $13.3 million, or 24.5%, compared to the nine months ended September 30, 2016. The decrease in our operating expenses was primarily due to the intangible asset impairment charge of $19.7 million during the nine months ended September 30, 2016. In addition, general and administrative expenses decreased by $4.6 million primarily due to a decrease in salary and benefit expense mostly from the retirement and separation of the former chief executive officer in the first quarter of 2016 and a decrease in professional fees related to legal and regulatory compliance activities. The decrease was offset by an increase in research and development expenses of $11.0 million primarily due to greater activity related to the development of our product candidates.

We also recognized a $6.9 million tax benefit during the nine months ended September 30, 2016, upon the reversal of our deferred tax liability, which solely relates to the indefinite-lived intangible assets.

Net loss attributable to common stockholders for the three months ended September 30, 2017 increased by $2.3 million. The increase in our net loss attributable to common stockholders was primarily due to increases in operating expenses of $3.6 million, offset by an increase in investment and other income of $0.3 million and a non-cash deemed dividend of $1.0 million related to the beneficial conversion feature on the Series D convertible preferred stock for the three months ended September 30, 2016.

Net loss attributable to common stockholders for the nine months ended September 30, 2017 decreased by $8.6 million. The decrease in our net loss attributable to common stockholders was primarily due to decreases in operating expenses of $13.3 million, lower non-cash deemed dividend of $1.6 million related to the beneficial conversion feature on convertible preferred stock, and higher investment and other income of $0.6 million, offset by a non-cash tax benefit of $6.9 million related to termination of the license agreement with STC.UNM for the nine months ended September 30, 2016.

Research and Development Expense

The following table summarizes the period over period changes in research and development expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In millions)		(In millions)	
Research and development	$ 10.9	$ 7.3	$ 31.0	$ 20.0

Research and development expenses are related primarily to the development of our clinical and pre-clinical stage programs. We do not currently utilize a formal time allocation system to capture expenses on a project-by-project basis because we are organized and record expense by functional area.

The following table summarizes our research and development expenses by functional area for the three and nine months ended September 30, 2017 and September 30, 2016:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In millions)		(In millions)	
External expenses [1]				
Clinical development expenses	$ 3.3	$ 2.0	$ 10.0	$ 6.1
Manufacturing expenses	1.9	1.7	6.2	3.2
Preclinical research expenses	1.6	0.6	2.7	1.4
License Fees / Milestones	0.1	—	0.1	(0.9)
Total external expenses	6.9	4.3	19.0	9.8
All other expenses [2]	4.0	3.0	12.0	10.2
Total research and development	$ 10.9	$ 7.3	$ 31.0	$ 20.0

[1] *External expenses include costs paid to outside parties for activities associated with our preclinical, clinical and manufacturing efforts as well as costs associated with licensing agreements we have entered into with third parties.*

[2] *All other expenses include personnel costs, stock compensation expenses, facility and equipment costs and other internal costs associated with our research and development activities.*

Research and development expenses incurred in the three months ended September 30, 2017 increased by $3.6 million, or 49.3%, compared to the three months ended September 30, 2016, due primarily to increases in clinical development expenses of $1.3 million and contract manufacturing expenses of $0.2 million related to contract clinical services associated with the ongoing tucatinib clinical trials, increases in other expenses of $1.0 million mostly due to increases in headcount and headcount-related expenses, and increases in preclinical research expenses of $1.0 million for laboratory services.

Research and development expenses incurred in the nine months ended September 30, 2017 increased by $11.0 million, or 55.0%, compared to the nine months ended September 30, 2016, due primarily to increases in clinical development expenses of $3.9 million and contract manufacturing expenses of $3.0 million related to contract clinical services associated with the ongoing tucatinib clinical trials, increases in other expense of $1.8 million mostly due to increases in headcount and headcount-related expenses, increases in preclinical research expenses of $1.3 million for laboratory services and license fees of $1.0 million primarily related to the reversal of the previously recorded time-based milestones for license fees in connection with our termination of the STC.UNM license agreement during nine months ended September 30, 2016.

General and Administrative Expense

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In millions)		(In millions)	
General and administrative	$ 3.4	$ 3.5	$ 9.9	$ 14.5

General and administrative expenses for the three months ended September 30, 2017 decreased by $0.1 million, or 2.9%, compared to the three months ended September 30, 2016.

General and administrative expenses for the nine months ended September 30, 2017 decreased by $4.6 million, or 31.7%, compared to the nine months ended September 30, 2016, primarily due to decreases in salary and benefit expense related to cash severance and insurance benefits of $1.6 million, non-cash compensation expense of $2.3 million due to the acceleration of share-based compensation as a result of the retirement and separation agreement that we entered into with our former chief executive officer in January 2016 and lower Retention Plan expenses of $0.4 million, offset by higher headcount and headcount-related expenses of $0.8 million. In addition, the decrease in general and administrative expenses was due to lower professional fees of $1.1 million for legal and regulatory compliance activities.

Intangible Assets Impairment

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In millions)		(In millions)	
Intangible asset impairment	$ —	$ —	$ —	$ (19.7)

During the three and nine months ended September 30, 2017, and the three months ended September 30, 2016, no impairment charges were recorded in our condensed consolidated statements of operations.

On May 5, 2016, we entered into an agreement with STC.UNM to mutually terminate the license agreement relating to protocell technology. As a result of the termination and our intent to no longer develop, license or commercialize the protocell technology, the indefinite-lived intangible assets, valued at $19.7 million were considered fully impaired. $19.7 million was fully written-off and recorded as intangible asset impairment in our condensed consolidated statements of operations during the nine months ended September 30, 2016. The indefinite-lived intangible assets represent the value assigned to in-process research and development when we acquired the protocell technology in connection with the acquisition of Alpine in 2014. For additional information, see "Note 12 — Collaborative and License Agreements" of the unaudited financial statements included in this report.

Investment and other income, net

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In millions)		(In millions)	
Investment and other income, net	$ 0.3	$ —	$ 0.7	$ 0.1

Net investment and other income increased by $0.3 million and $0.6 million for the three and nine months ended September 30, 2017 compared to the three and nine months ended September 30, 2016, respectively, primarily due to higher interest income.

Income Tax Benefit

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In millions)		(In millions)	
Income tax benefit	$ —	$ —	$ —	$ (6.9)

During the three and nine months ended September 30, 2017, and the three months ended September 30, 2016, no income tax benefit or provision were recorded in our condensed consolidated statements of operations.

Due to the $19.7 million impairment of indefinite-lived intangible assets, we reversed our deferred tax liability, which solely relates to the indefinite-lived intangible assets, and recorded a $6.9 million tax benefit in our condensed consolidated statements of operations for the nine months ended September 30, 2016. For additional information, see "Note 12 — Collaborative and License Agreements" of the unaudited financial statements included in this report.

Deemed Dividend on Convertible Preferred Stock

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
	(In millions)		(In millions)	
Deemed dividend on convertible preferred stock	$ —	$ (1.0)	$ (1.0)	$ (2.6)

During the three months ended September 30, 2017, there were no deemed dividends related to convertible preferred stock recorded in our condensed consolidated statements of operations. During the nine months ended September 30, 2017, we recognized a beneficial conversion feature in the amount of $1.0 million, calculated as the number of potential conversion shares multiplied by the excess of the market price of its common stock over the price per conversion share of the Series E convertible preferred stock on the commitment date. The non-cash dividend was recorded in additional paid-in capital and as a deemed dividend on the Series E convertible preferred stock, and was used in determining the net loss applicable to common stockholders in the condensed consolidated statement of operations.

During the nine months ended September 30, 2016, we recognized a beneficial conversion feature in the amount of $2.6 million, calculated as the number of potential conversion shares multiplied by the excess of the market price of its common stock over the price per conversion share of the Series D convertible preferred stock on the commitment date. In the second quarter of 2016, we immediately accreted $1.6 million of the $2.6 million beneficial conversion feature, representing approximately 60% of the Series D convertible preferred stock that could be converted at that time, upon issuance. We accreted the remaining $1.0 million beneficial conversion feature, representing 40% of the Series D convertible preferred stock that could not be converted upon issuance due to certain contractual limitations, from the issuance date to the earliest conversion date, which fell within the third quarter of 2016. Non-cash deemed dividend expense of $1.0 million and $2.6 million was recorded in additional paid-in capital and as a deemed dividend on the Series D convertible preferred stock, and was used in determining the net loss applicable to common stockholders in the consolidated statement of operations for the three and nine months ended September 30, 2016, respectively.

Liquidity and Capital Resources

Cash, Cash Equivalents, Investments and Working Capital

As of September 30, 2017, our principal sources of liquidity consisted of cash and cash equivalents of $12.7 million, short-term investments of $89.3 million and long-term investments of $11.0 million. Our cash and cash equivalents consist of cash, money market funds and securities with an initial maturity of less than 90 days. Our short-term investments are invested in debt securities of U.S government agencies and corporate bonds with maturities not exceeding 12 months from September 30, 2017. Our long-term investments are invested in debt securities of U.S government agencies with maturities exceeding 12 months from September 30, 2017. Our primary source of cash has historically been proceeds from the sale of our equity securities, cash received through our strategic partners, government grants, debt financings and equipment financings. These proceeds have been used to fund our operations.

Our cash and cash equivalents were $12.7 million as of September 30, 2017 compared to $13.7 million as of December 31, 2016, a decrease of $1.0 million, or 7.3%. The decrease was the result of cash used to fund our operations of $37.2 million, net investment purchases of $51.2 million and purchases of property and equipment of $0.5 million, offset by net proceeds of $88.0 million from our January 2017 financing.

As of September 30, 2017, our working capital (defined as current assets less current liabilities) was $94.8 million compared to $55.7 million as of December 31, 2016, an increase of $39.1 million, or 70.2%. The increase in working capital was primarily attributable to an increase in short-term investments of $40.2 million, offset by a decrease in cash and cash equivalents of $1.0 million.

On January 27, 2017, we closed an underwritten offering of 26,659,300 shares of our common stock at a price to the public of $3.30 per share, for gross proceeds of approximately $88.0 million. The shares included 3,477,300 shares of common stock sold pursuant to the over-allotment option granted by us to the underwriters, which option was exercised in full. In addition, we closed a concurrent underwritten offering of 1,818 shares of our Series E convertible preferred stock at a price to the public of $3,300 per share, for gross proceeds of approximately $6.0 million. Each share of Series E convertible preferred stock is non-voting and convertible into 1,000 shares of our common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would beneficially own more than 19.99% of the common stock then outstanding. Aggregate gross proceeds from the offerings were approximately $94.0 million. Aggregate net proceeds from the offerings, after underwriting discounts and commissions and other expenses of $6.0 million, were approximately $88.0 million.

On June 28, 2016, we closed an underwritten public offering of 6,708,333 shares of our common stock at a price to the public of $4.80 per share for gross proceeds of $32.2 million. The shares included 875,000 shares of common stock sold pursuant to the over-allotment option granted by us to the underwriters, which option was exercised in full. In addition, we closed a registered direct offering of 17,250 shares of our Series D convertible preferred stock at a price of $800.00 per share directly to affiliates of BVF for gross proceeds of $13.8 million. Each share of Series D convertible preferred stock is non-voting and convertible into 166.67 shares of our common stock, provided that conversion will be prohibited if, as a result, the holder and its affiliates would beneficially own more than 19.99% of the common stock then outstanding. Aggregate gross proceeds from the offerings were approximately $46.0 million. Aggregate net proceeds from the offerings, after underwriting discounts and commissions and other expenses of $2.7 million, were approximately $43.3 million.

We believe that our currently available cash and cash equivalents and investments as of September 30, 2017 will be sufficient to finance our operations for at least the next 12 months. Nevertheless, we expect that we will require additional capital from time to time in the future in order to continue the development of products in our pipeline and to expand our product portfolio. We would expect to seek additional financing from business development activities and the sale and issuance of equity or debt securities.

Cash Flows from Operating Activities

Cash used by operating activities totaled $37.2 million for the nine months ended September 30, 2017, compared to $28.0 million for the nine months ended September 30, 2016. The increase was attributable primarily to an increase in research and development expenses associated with ongoing tucatinib clinical trials.

Cash Flows from Investing Activities

Cash used in investing activities was $51.7 million for the nine months ended September 30, 2017, compared to $26.8 million for the nine months ended September 30, 2016. This change was attributable primarily to higher purchases of investments, net of redemption, of $51.2 million for the nine months ended September 30, 2017 as compared to $26.7 million for the nine months ended September 30, 2016, and an increase in purchases of property and equipment of $0.5 million during the nine months ended September 30, 2017 compared to the same period in 2016.

Cash Flows from Financing Activities

Cash provided by financing activities during the nine months ended September 30, 2017consisted of net proceeds of $88.0 million from our January 2017 concurrent underwritten common stock and Series E convertible preferred stock offerings. Net proceeds from our common stock offering were $82.4 million and net proceeds from our Series E convertible preferred stock offering were approximately $5.6 million.

Cash provided by financing activities was $43.5 million during the nine months ended September 30, 2016, which consisted primarily of $43.3 million of net proceeds from our June 2016 underwritten common stock and registered direct Series D convertible preferred stock offerings and $0.2 million of proceeds from the settlement of a short-swing profit claim in August 2016. Net proceeds from our common stock offering were $29.8 million and net proceeds from our Series D convertible preferred stock offering were approximately $13.5 million.

Contractual Obligations and Contingencies

In our continuing operations, we have entered into long-term contractual arrangements from time to time for our facilities, the provision of goods and services, and acquisition of technology access rights, among others.

In May 2008, we entered into a lease for an office and laboratory facility in Seattle, Washington totaling approximately 17,000 square feet. In November 2016, we entered into an amendment to our existing lease to add approximately 2,600 square feet of office space. The lease provides for a base monthly rent of $47,715, increasing to $57,910 in 2018. We also have entered into operating lease obligations through November 2019 for certain office equipment.

In addition to the obligations described above, under certain licensing arrangements for technologies incorporated into our product candidates, we are contractually committed to payments for licensing fees and royalties, as well as contingent payments if certain milestones (as defined in the agreements) have been achieved. The achievement of milestones is subject to numerous factors, and we cannot predict when or if such milestones will be achieved.

As of September 30, 2017, no significant milestones, as defined in the agreements, were achieved and, as such, we are not currently contractually committed to any significant quantifiable payments for licensing fees, royalties or other contingent payments.

We also enter into contracts in the ordinary course of our business such as clinical research organization service contracts and manufacturing service contracts. These contracts are fee for service contracts that are terminable at will by us, and do not provide for fixed payments to be made at specific intervals. Payments for these contracts are expensed in the period that the service is incurred.

Guarantees and Indemnification

In the ordinary course of our business, we have entered into agreements with our collaboration partners, vendors, and other persons and entities that include guarantees or indemnity provisions. For example, our agreements with clinical trial sites and third-party manufacturers contain certain customary indemnification provisions, and we have entered into indemnification agreements with our officers and directors. Based on information known to us as of the filing date of this report we believe that our exposure related to these guarantees and indemnification obligations is not material.

Off-Balance Sheet Arrangements

During the periods presented, we did not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for another contractually narrow or limited purpose.

Recent Accounting Pronouncements

In January 2017, the FASB issued ASU 2017-04, Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. This standard simplifies the subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test which previously required measurement of any goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. Instead, under this update, the impairment charge will be measured based on the excess of a reporting unit's carrying value over its fair value. The standard will be applied prospectively and is effective for a public business entity that is an SEC filer for its annual and interim impairment tests performed in periods beginning after December 15, 2019. Early adoption is permitted for annual and interim goodwill impairment testing dates after January 1, 2017. We are currently evaluating any impact this standard may have on our consolidated financial position and results of operations.

In March 2016, the FASB issued Accounting Standards Update (ASU) 2016-09, Improvements to Employee Share-Based Payment Accounting, which amends ASC Topic 718, Compensation – Stock Compensation. The guidance changes how companies account for certain aspects of share-based payments to employees including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The guidance is effective for public business entities for fiscal years beginning after December 15, 2016, and interim periods within those years. We adopted this standard as of January 1, 2017. Because we have incurred net losses since our inception and maintain a full valuation allowance on our net deferred tax assets, the adoption of this standard does not have a material impact on our financial condition, results of operations and cash flows, or financial statement disclosures.

In August 2015, FASB issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606)—Deferral of the Effective Date, which defers by one year the effective date of ASU 2014-09, Revenue from Contracts with Customers. For public entities, the standard is effective for annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Early adoption is permitted as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within those annual periods. As we do not currently have any revenue arrangements in the scope of the new revenue standard, we do not expect the adoption of this standard to have a material effect on our financial position or results of operations. However, if we do enter into license, collaboration or other revenue arrangements during 2017, there may be material differences in the accounting treatment under the current guidance and the new revenue standard as of the adoption date, January 1, 2018.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Sensitivity

We had cash, cash equivalents, short-term investments and long-term investments totaling $113.0 million and $62.8 million as of September 30, 2017 and December 31, 2016, respectively. We do not enter into investments for trading or speculative purposes. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates since a majority of these assets are of a short-term nature. Declines in interest rates, however, would reduce future investment income. A ten basis point decline in interest rates, occurring January 1, 2017 and sustained throughout the period ended September 30, 2017, would result in a decline in investment income of approximately $66,000 for that period.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness, as of the end of the period covered by this report, of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act). The purpose of this evaluation was to determine whether as of the evaluation date our disclosure controls and procedures were effective to provide reasonable assurance that the information we are required to disclose in our filings with the SEC under the Exchange Act (1) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, our chief executive officer and chief financial officer have concluded that, as of September 30, 2017, our disclosure controls and procedures were effective.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the three months ended September 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitation on the Effectiveness of Internal Controls

The effectiveness of any system of internal control over financial reporting, including ours, is subject to inherent limitations, including the exercise of judgment in designing, implementing, operating, and evaluating the controls and procedures, and the inability to eliminate misconduct completely. Accordingly, any system of internal control over financial reporting, including ours, no matter how well designed and operated, can only provide reasonable, not absolute assurances. In addition, projections of any evaluation of effectiveness 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. We intend to continue to monitor and upgrade our internal controls as necessary or appropriate for our business, but cannot assure that such improvements will be sufficient to provide us with effective internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in litigation relating to claims arising out of our operations in the normal course of business. We are not currently a party to any legal proceedings, the adverse outcome of which, in management's opinion, individually or in the aggregate, would have a material adverse effect on the results of our operations or financial position. There are no material proceedings to which any director, officer or any of our affiliates, any owner of record or beneficially of more than five percent of any class of our voting securities, or any associate of any such director, officer, our affiliates, or security holder, is a party adverse to us or our consolidated subsidiary or has a material interest adverse to the Company or such subsidiary.

Item 1A. Risk Factors

Set forth below and elsewhere in this report, and in other documents we file with the SEC, are descriptions of risks and uncertainties that could cause actual results to differ materially from the results contemplated by the forward-looking statements contained in this report. Because of the following factors, as well as other variables affecting our operating results, past financial performance should not be considered a reliable indicator of future performance and investors should not use historical trends to anticipate results or trends in future periods. The risks and uncertainties described below are not the only ones facing us. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition.

Risks Relating to our Business

Product candidates that appear promising in research and development may be delayed or may fail to reach later stages of clinical development.

The successful development of pharmaceutical products is highly uncertain. Product candidates that appear promising in research and development may be delayed or fail to reach later stages of development. For example, preliminary data from our Phase 1b trial of ONT-10 in combination with the T-cell agonist antibody, varlilumab, did not demonstrate sufficient activity to move forward with the program. We, therefore, decided not to continue this trial and, in February 2016, we terminated our collaboration agreement with Celldex. The ongoing or future trials for tucatinib (ONT-380) and our other programs may fail to demonstrate that these product candidates are sufficiently safe and effective to warrant further development.

Furthermore, decisions regarding the further development of product candidates must be made with limited and incomplete data, which makes it difficult to accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Preclinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent the development of a product candidate, which could harm our business, financial condition or the trading price of our securities. There can be no assurance as to whether or when we will receive regulatory approvals for any of our product candidates, including tucatinib, CASC-578 and CASC-674.

There is no assurance that tucatinib will be safe, effective or receive regulatory approval for any indication.

Tucatinib is a late-stage clinical development candidate and the risks associated with its development are significant. Promising preclinical data in animal models and early clinical data may not be predictive of later clinical trial results. Clinical data from our pivotal HER2CLIMB clinical trial may fail to establish that tucatinib is effective in treating HER2+ breast cancer or associated brain metastases or may indicate safety profile concerns not indicated by earlier clinical data.

In December 2014, we announced that interim data from our ongoing Phase 1b combination trials indicated preliminary clinical activity and tolerability in a heavily pretreated patient population. Updates to some of these data provided further preliminary evidence of clinical activity and tolerability, including in brain metastases. Based upon this data, we commenced a Phase 2 clinical trial of tucatinib in February 2016 and are continuing that trial as our pivotal HER2CLIMB trial. However, none of these trials are complete, and even if final Phase 1b data are encouraging, the results from the pivotal HER2CLIMB clinical trial and any other clinical trials may not indicate a favorable safety and efficacy profile for tucatinib or may otherwise fail to support continued development of this product candidate.

In December 2016, we announced that, following discussions with the Food and Drug Administration (FDA) and discussions with our external Steering Committee, we amended the HER2CLIMB clinical trial of tucatinib by increasing the sample size so that, if successful, the trial could serve as a single pivotal study to support a new drug application. The primary endpoint remains progression-free survival (PFS) and the sample size has been increased to approximately 480 patients from 180 patients. Patients will also be followed for overall survival which is a secondary endpoint. Key objectives related to assessing activity in brain metastases include a secondary endpoint of PFS in a subset of patients with brain metastases. There is no assurance that the clinical data will achieve these endpoints in whole or in part. For example, the clinical data may achieve the primary endpoint in the overall study population, but not achieve the secondary endpoint in patients with brain metastases. We have not received a Special Protocol Assessment for the HER2CLIMB study. Thus, even if some or all of the endpoints are achieved and we file an NDA seeking approval for the commercial sale of tucatinib in metastatic breast cancer, there is no assurance that the FDA will approve the application.

In June 2017, an investigator-sponsored trial was initiated to evaluate tucatinib in patients with colorectal cancer. Additional investigator-sponsored clinical trials of tucatinib in other indications may also be initiated in the future. We may also initiate additional clinical trials of tucatinib. Data from clinical trials we or investigators may initiate in other indications may fail to demonstrate that tucatinib is effective in the indications studied or safety profile concerns may arise. In that event, even if the pivotal HER2CLIMB succeeds in reaching its endpoints and receives regulatory approval, we may not be able to continue development of tucatinib in other indications or to receive regulatory approval for additional indications, which may limit the commercial potential of tucatinib and harm our business.

Reports of adverse events or safety concerns involving tucatinib could delay or prevent us from obtaining regulatory approval.

Reports of adverse events or safety concerns involving tucatinib or the combination of tucatinib with capecitabine or trastuzumab being studied in the HER2CLIMB study or the combination of tucatinib with other drugs could interrupt, delay or halt the HER2CLIMB clinical trial and/or other clinical trials of tucatinib. Tucatinib alone and in combination with other drugs has been studied in a limited number of patients to date and the known safety information is correspondingly limited. With study in additional patients, more severe or unanticipated adverse events may be experienced by patients. Reports of adverse events or safety concerns involving tucatinib could result in regulatory authorities denying approval of tucatinib or limiting its use. There are no assurances that patients receiving tucatinib in combination with other drugs will not experience serious adverse events in the future or that unexpected or unanticipated adverse events will not occur. Further, there are no assurances that patients receiving tucatinib with co-morbid diseases will not experience new or different serious adverse events in the future.

Adverse events may also negatively impact the sales of tucatinib, if it is approved for sale in any jurisdiction. If tucatinib is approved for sale in the United States, we could be required to implement a Risk Evaluation and Mitigation Strategy to address safety concerns, which could adversely affect tucatinib's acceptance in the market, make competition easier or make it more difficult or expensive for us to distribute and sell tucatinib.

We rely on agreements with third parties for our product candidate technology. Failure to maintain those agreements could prevent us from continuing to develop and commercialize our product candidates.

We entered into an exclusive license agreement with Array BioPharma, Inc. for our tucatinib technology. If Array BioPharma were to terminate our license agreement or if we are unable to maintain the exclusivity of that license agreement, we may be unable to continue to develop tucatinib. Further, we may in the future have a dispute with Array BioPharma which may impact our ability to develop and commercialize tucatinib or require us to enter into additional licenses.

We also have an exclusive license from Sentinel Oncology for our Chk1 program. If Sentinel Oncology were to terminate our license agreement or if we are unable to maintain the exclusivity of that license agreement, we may lose our rights to CASC-578. Further, we may in the future have a dispute with Sentinel Oncology which may adversely impact our business objectives regarding CASC-578 or require us to enter into additional licenses.

We also have a development and option agreement for our CASC-674 program with Adimab. If Adimab were to terminate that agreement or if we do not exercise our option to acquire a license from Adimab, we may be unable to continue our CASC-674 program. Further, even if we exercise our option we may in the future have a dispute with Adimab which may adversely impact our business objectives regarding CASC-674 or require us to enter into additional licenses.

An adverse result in potential future disputes with our licensors and partners may impact our ability to develop and commercialize tucatinib and our other product candidates, may require us to enter into additional licenses, or may require us to incur additional costs in litigation or settlement. In addition, continued development and commercialization of tucatinib and our other product candidates may require us to secure licenses to additional technologies. We may not be able to secure these licenses on commercially reasonable terms, if at all.

Our ability to continue with our planned operations is dependent on our success at raising additional capital sufficient to meet our obligations on a timely basis. If we fail to obtain additional financing when needed, we may be unable to complete the development, regulatory approval and commercialization of our product candidates.

We have expended and will continue to expend substantial funds in connection with our product development activities and clinical trials and regulatory approvals. Conducting a large pivotal trial and other clinical trials and IND-enabling studies is very costly and our funds are very limited. Accordingly, to commercialize tucatinib, if our HER2CLIMB trial is successful, to continue tucatinib's development into other indications, and to fund the continued development of our other programs, we will need to raise additional funds from the sale of our securities, partnering arrangements or other financing transactions in order to finance the commercialization of tucatinib and our other product candidates. We cannot be certain that additional financing will be available when and as needed or, if available, that it will be available on acceptable terms. If financing is available, it may be on terms that adversely affect the interests of our existing stockholders or restrict our ability to conduct our operations. To the extent that we raise additional funds through collaboration and licensing arrangements, we may be required to relinquish some rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. Our actual capital requirements will depend on numerous factors, including:

- the pace of enrollment in the HER2CLIMB trial and the actual costs of that trial;
- whether we enter into licensing or collaboration arrangements for any of our product candidates that reduce our costs to develop those product candidates;
- activities and arrangements related to the commercialization of our product candidates;
- the progress of our research and development programs;
- the progress of preclinical and clinical testing of our product candidates;

- the time and cost involved in obtaining regulatory approvals for our product candidates;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights with respect to our intellectual property;
- the effect of competing technological and market developments;
- the effect of changes and developments in our existing licensing and other relationships; and
- the terms of any new collaborative, licensing and other arrangements that we may establish.

If we require additional financing and cannot secure sufficient financing on acceptable terms, we may need to delay, reduce or eliminate some or all of our research and development programs, any of which could have a material adverse effect on our business and financial condition.

We have a history of net losses, we anticipate additional losses and we may never become profitable.

Other than the year ended December 31, 2008, we have incurred net losses in each fiscal year since we commenced our research activities, and we do not anticipate realizing net income for the foreseeable future. As of September 30, 2017, our accumulated deficit was approximately $612.5 million. Our losses have resulted primarily from expenses incurred in research and development of our product candidates. We make significant capital commitments to fund the development of our product candidates. If these development efforts are unsuccessful, the development costs would be incurred without any future revenue, which could have a material adverse effect on our financial condition. We do not know when or if we will complete our product development efforts, receive regulatory approval for any of our product candidates, or successfully commercialize any approved products. As a result, it is difficult to predict the extent of any future losses or the time required to achieve profitability, if at all. Any failure of tucatinib or our other product candidates to complete successful clinical trials and obtain regulatory approval and any failure to become and remain profitable could adversely affect the price of our common stock and our ability to raise capital and continue operations.

We may be unable to enter into licensing or collaboration relationships.

We may from time to time seek to enter into licensing or collaboration relationships. Proposing, negotiating and implementing an economically viable licensing or collaboration arrangement is a lengthy and complex process. We compete for partnering arrangements and license agreements with pharmaceutical and biotechnology companies and other institutions. Our competitors may have stronger relationships with third parties with whom we are interested in collaborating or may have more established histories of developing and commercializing products. As a result, our competitors may have a competitive advantage in entering into partnering or licensing arrangements with such third parties. In addition, even if we generate interest in a partnering or licensing arrangement, we may not be able to enter into such arrangements on terms that we find acceptable, if at all. If we do enter into such arrangements, our obligations under the arrangement may require commitments of time and resources that may additional resources.

The failure to enroll patients in the HER2CLIMB study or in other clinical trials may cause delays in developing our product candidates.

We may encounter delays if we are unable to enroll enough patients to timely complete the pivotal HER2CLIMB clinical trial or any of our other clinical trials. Patient enrollment depends on many factors, including the size of the patient population, the ability to engage clinical sites, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial, and competition for patients with competing trials. The HER2CLIMB clinical trial has specific criteria for enrollment that may limit the number of patients eligible to participate in the trial and only a small fraction of potentially eligible patients in a given patient population ever seek to participate in a clinical trial. We undertake feasibility studies to help us determine the number of investigative sites required to enroll the patients needed for a given clinical trial, but the results of those studies are estimates and enrollment may be substantially slower than anticipated. Moreover, when one product candidate is evaluated in multiple clinical trials, patient enrollment in ongoing trials can be adversely affected by negative results from completed trials. Our product candidates are focused in oncology, which can be a difficult patient population to recruit. If we fail to enroll patients for HER2CLIMB or our other clinical trials, HER2CLIMB or our other clinical trials may be delayed or suspended, which could delay our ability to generate revenues or raise capital to fund our operations. To enroll patients, we may have to seek additional clinical sites which cause additional expense and time with no guarantee of recruiting patients to our trials.

There is no assurance that we will be granted regulatory approval for tucatinib for metastatic breast cancer or any other indication or be granted regulatory approval for any of our other product candidates.

We are currently conducting a pivotal clinical trial and following patients in Phase 1b trials of tucatinib. There can be no assurance that these and future studies and trials will demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals. A number of companies in the biotechnology and pharmaceutical industries, including our company, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials.

Further, we may be unable to submit applications to regulatory agencies within the time frame we currently expect. Once submitted, applications must be approved by various regulatory agencies before we can commercialize the product described in the application. Additionally, even if applications are submitted, regulatory approval may not be obtained for any of our product candidates, and regulatory agencies could require additional clinical trials to verify safety or efficacy, which could make further development of our product candidates impracticable. If our product candidates are not shown to be safe and effective in clinical trials, we may not receive regulatory approval, which would have a material adverse effect on our business, financial condition and results of operations.

We currently rely on third-party manufacturers and other third parties to manufacture, package and supply tucatinib. Any disruption in production, inability of these third parties to produce adequate, satisfactory quantities to meet our needs or other impediments with respect to, manufacturing and supply could adversely affect our ability to continue the HER2CLIMB and other clinical trials of tucatinib, delay submissions of our regulatory applications or adversely affect our ability to commercialize tucatinib in a timely manner, or at all.

We are responsible for the manufacturing, labeling, packaging and distribution of tucatinib, which we outsource to third parties. Manufacture and supply of drug products such as tucatinib is a complex process involving multiple steps and multiple manufacturers and service providers. If our third-party manufacturers cease or interrupt production, if our third-party manufacturers and other service providers fail to supply satisfactory materials, products or services for any reason or experience performance delays or quality concerns, or if materials or products are lost in transit or in the manufacturing process, such interruptions could substantially delay progress on our programs or impact clinical trial drug supply, with the potential for additional costs and a material adverse effect on our business, financial condition and results of operations.

Our product candidates have not yet been manufactured on a commercial scale. Manufacturing at commercial scale may require third-party manufacturers to increase manufacturing capacity, which may require the manufacturers to fund capital improvements to support the scale up of manufacturing and related activities. With respect to a product candidate, we may be required to provide all or a portion of these funds. Third-party manufacturers may not be able to successfully increase manufacturing capacity for a product candidate for which we obtain marketing approval in a timely or economic manner, or at all. If any manufacturer is unable to provide commercial quantities of a product candidate, we will need to successfully transfer manufacturing technology to a new manufacturer. Engaging a new manufacturer for a particular product candidate could require us to conduct comparative studies or use other means to determine equivalence between that product candidate manufactured by a new manufacturer and the product candidate manufactured by the existing manufacturer, which could delay or prevent commercialization of our product candidate. If any of these manufacturers is unable or unwilling to increase its manufacturing capacity or if alternative arrangements are not established on a timely basis or on acceptable terms, the development and commercialization of the particular product candidate may be delayed or there may be a shortage in supply.

Manufacturers of our product candidates and related service providers must comply with GMP requirements enforced by the FDA through its facilities inspection program or by foreign regulatory agencies. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our products and related service providers may be unable to comply with these GMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' or service providers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, or restrictions on the use of products produced, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any quantities supplied is compromised due to our manufacturers' or other service providers' failure to adhere to GMP or other applicable laws or for other reasons, we may not be able to obtain regulatory approval for our product candidates, the development and commercialization of our product candidates may be delayed and there may be a shortage in supply, which may prevent successful commercialization of our products.

Preclinical and clinical trials are expensive and time consuming, and any failure or delay in commencing or completing clinical trials for our product candidates could severely harm our business.

We are currently conducting a pivotal Phase 2 clinical trial and following patients in ongoing Phase 1b clinical trials for tucatinib. Each of our product candidates must undergo extensive preclinical studies and clinical trials as a condition to regulatory approval. Preclinical studies and clinical trials are expensive and take many years to complete. The commencement and completion of clinical trials for our product candidates may be delayed by many factors, including:

- safety issues or side effects;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- our ability to engage to timely engage suitable clinical trial sites that have personnel with the expertise required to conduct our clinical trial;

- poor effectiveness of product candidates during clinical trials;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- our ability to satisfy regulatory requirements to commence a clinical trial and conduct the clinical trial in accordance with good clinical practices;
- our ability to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials; and
- varying interpretation of data by the FDA and similar foreign regulatory agencies.

It is possible that none of our product candidates will complete clinical trials in any of the markets in which we intend to sell those product candidates. Accordingly, we may not receive the regulatory approvals necessary to market our product candidates. Any failure or delay in commencing or completing clinical trials or obtaining regulatory approvals for product candidates would prevent or delay their commercialization and severely harm our business and financial condition.

In addition, both prior to and after regulatory approval of a product, regulatory agencies may require us to delay, restrict or discontinue clinical trials on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. In addition, all statutes and regulations governing the conduct of clinical trials are subject to change in the future, which could affect the cost of such clinical trials. Any unanticipated delays in clinical studies could delay our ability to generate revenues and harm our financial condition and results of operations.

We rely on third parties to conduct our clinical trials. If these third parties do not perform as contractually required or otherwise expected, we may not be able to obtain regulatory approval for or be able to commercialize our product candidates.

We rely on third parties, such as contract research and clinical organizations, medical institutions, clinical investigators and contract laboratories, to assist in conducting our clinical trials. We have, in the ordinary course of business, entered into agreements with these third parties. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA and foreign regulatory agencies require us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

We may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity, for tucatinib, and may be unsuccessful in obtaining orphan drug designation or transfer of designations obtained by others for future product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs intended to treat relatively small patient populations as orphan drugs. Under the U.S. Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals 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 credits for qualified clinical research costs, and prescription drug user fee waivers.

Generally, if a drug with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. If our competitors are able to obtain orphan drug exclusivity prior to us for products that constitute the same active moiety and treat the same indications as our product candidates, we may not be able to have competing products approved by the applicable regulatory authority for a significant period of time. The applicable period is seven years in the United States.

As part of our business strategy, we have sought and received orphan drug designation for tucatinib in the United States for the treatment of HER2+ colorectal cancer and the treatment of breast cancer patients with brain metastases. However, orphan drug designation does not guarantee future orphan drug marketing exclusivity.

Additionally, even though we have obtained an orphan drug designation for tucatinib, and even if we obtain orphan drug exclusivity for this product candidate and other product candidates, that exclusivity may not effectively protect tucatinib from competition because drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can also subsequently approve a later application for a drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation does not shorten the development time or regulatory review time of a drug and does not give the drug any advantage in the regulatory review or approval process.

Our product candidates may never achieve market acceptance even if we obtain regulatory approvals.

Even if we receive regulatory approvals for the commercial sale of our product candidates, the commercial success of these product candidates will depend on, among other things, their acceptance by physicians, patients, third-party payers such as health insurance companies, and other members of the medical community as a therapeutic and cost-effective alternative to competing products and treatments. New patterns of care, alternative new treatments or different reimbursement and payer paradigms, possibly due to economic conditions or governmental policies, could negatively impact the commercial viability of our product candidates. If our product candidates fail to gain market acceptance, we may be unable to earn sufficient revenue to continue our business. Market acceptance of, and demand for, any product that we may develop and commercialize will depend on many factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of adverse side effects;
- availability, relative cost and relative efficacy of alternative and competing treatments;
- the effectiveness of our marketing and distribution strategy;
- publicity concerning our products or competing products and treatments; and
- our ability to obtain sufficient third-party insurance coverage or reimbursement.

If our product candidates do not become widely accepted by physicians, patients, third-party payers and other members of the medical community, our business, financial condition and results of operations would be materially and adversely affected.

Even if regulatory approval is received for our product candidates, we are subject to ongoing regulatory obligations that, if not met, may adversely affect our ability to commercialize an approved product.

We are subject to ongoing regulatory obligations following approval of a product including potential requirements for additional clinical trials, ongoing GMP manufacturing requirements, and other requirements. If a product is approved for commercial sale, safety concerns may arise that were not present in clinical trials or occur at higher rates than in our clinical trials of the product which may result in regulatory restrictions. In addition, reports of adverse events or safety concerns could result in the FDA or other regulatory authorities denying or withdrawing approval of the product for any or all indications. There is no assurance that patients will not experience such adverse events or safety concerns.

In addition, we will be required to comply with other limitations and restrictions imposed by U.S., state and foreign governments in connection with the marketing of an approved product and reimbursement for approved products. Our failure to meet any of these requirements may have an adverse effect on our ability to commercialize an approved product and our business would suffer.

In addition, if we fail to comply with any applicable requirements, we could be subject to penalties, including:

- warning letters;
- untitled letters;
- suspension of clinical trials;
- product liability litigation;
- total or partial suspension of manufacturing or costly new manufacturing requirements;
- fines;
- product recalls;
- withdrawal of regulatory approval;
- operating restrictions;

- disgorgement of profits;
- injunctions; and
- criminal prosecution.

Any of these penalties may result in substantial costs to us and could adversely affect our ability to commercialize an approved product and our business would suffer.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products internationally.

We intend to have our product candidates marketed outside the United States. In order to market our products in the European Union and many other non-U.S. jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. To date, we have not filed for marketing approval for any of our product candidates and may not receive the approvals necessary to commercialize our product candidates in any market.

The approval procedure varies among countries and may include all the risks associated with obtaining FDA approval. The time required to obtain foreign regulatory approval may differ from that required to obtain FDA approval, and additional clinical trials, testing and data review may be required. We may not obtain foreign regulatory approvals on a timely basis, if at all. Additionally, approval by the FDA does not ensure approval by regulatory agencies in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory agencies in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in other jurisdictions, including approval by the FDA. The failure to obtain regulatory approval in foreign jurisdictions could limit commercialization of our products, reduce our ability to generate profits and harm our business.

We may expand our business through the acquisition of companies or businesses or by entering into collaborations or in-licensing product candidates that could disrupt our business and harm our financial condition.

We have in the past and may in the future seek to expand our pipeline and capabilities by acquiring one or more companies or businesses, entering into collaborations or in-licensing one or more product candidates. For example, in December 2014, we entered into a license agreement with Array for exclusive rights to develop and commercialize tucatinib. Acquisitions, collaborations and in-licenses involve numerous risks, including:

- substantial cash expenditures;
- potentially dilutive issuance of equity securities;
- incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition;
- potential adverse consequences if the acquired assets are worth less than we anticipated or we are unable to successfully develop and commercialize the acquired assets for any reason;
- difficulties in assimilating the operations and technology of the acquired companies;
- potential disputes, including litigation, regarding contingent consideration for the acquired assets;
- the assumption of unknown liabilities of the acquired businesses;
- diverting our management's attention away from other business concerns;
- entering markets in which we have limited or no direct experience; and
- potential loss of our key employees or key employees of the acquired companies or businesses.

Our experience in making acquisitions, entering collaborations and in-licensing product candidates is limited. We cannot assure you that any acquisition, collaboration or in-license will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, our future success may depend in part on our ability to manage the growth and technology integration associated with any of these acquisitions, collaborations and in-licenses. We cannot assure you that we will be able to successfully combine our business with that of acquired businesses, manage collaborations or integrate in-licensed product candidates or that such efforts would be successful. Furthermore, the development or expansion of our business or any acquired business or company or any collaboration or in-licensed product candidate may require a substantial capital investment by us. We may also seek to raise funds by selling shares of our capital stock, which could dilute our current stockholders' ownership interest, or securities convertible into our capital stock, which could dilute current stockholders' ownership interest upon conversion. We may also incur debt obligations, which could require us to comply with covenants which could restrict our ability to operate our business and negatively impact the value of our common stock.

Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection worldwide with respect to our proprietary technology and products that are important to our business.

Our ability to successfully commercialize our technology and products and to compete effectively may be materially adversely affected if we are unable to obtain and maintain effective intellectual property rights to our technologies and product candidates throughout the world. The intellectual property position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions. The process of filing patent applications in the United States and abroad is expensive and time-consuming, and we or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

In recent years, there have been significant changes in both the patent laws and interpretation of the patent laws in the United States and other countries. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to obtain and maintain patent protection for our products and could prevent us from effectively blocking others from commercializing competitive technologies and products or limit the duration of the patent protection for our technology and products.

Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

We have in-licensed or acquired a portion of our intellectual property necessary to develop certain of our product candidates. If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose such licenses or intellectual property rights that are important to our business.

We are a party to intellectual property license agreements with other parties, including with respect to tucatinib, and expect to enter into additional license agreements in the future. In some circumstances, we may not have the right to enter into additional license agreements in the future. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology or products that we license from third parties. Therefore, we cannot be certain that these patents and applications will be prosecuted and enforced in a manner consistent with the best interests of our business. In addition, if the parties who license patents to us fail to maintain such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated. If we fail to meet our obligations in our license agreements, our licensors may have the right to terminate these agreements, in which event we may lose intellectual property rights to a product candidate that is covered by the agreement. Termination of these licenses or reduction or elimination of our licensed rights may result in our having to negotiate new or reinstated licenses with less favorable terms or our not having sufficient intellectual property rights to operate our business.

Protection of trade secrets and confidential information is difficult and we may not be successful in protecting our rights to our unpatented proprietary know-how and trade secrets, thus harming our business and competitive position.

We rely on unpatented proprietary know-how, trade secrets and continuing technological innovations to develop and maintain our competitive position. We employ various methods, including confidentiality agreements with employees and consultants, customers, suppliers and potential collaborators to protect our know-how and trade secrets. However, these agreements may not adequately protect us or provide an adequate remedy. Our trade secrets or know-how may become known or be independently discovered by our competitors. Unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and lose their value if they are discovered or disclosed.

Further, we may not be able to deter current and former employees, contractors and other parties from breaching confidentiality agreements and misappropriating our proprietary information. It is possible that other parties may copy or otherwise obtain and use our information and proprietary technology without authorization.

We may be subject to claims that our employees have wrongfully used or disclosed intellectual property of their former employers, which may cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Many of our employees were previously employed at universities or other companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others, we may be subject to claims that we or our employees have used or disclosed proprietary information of a former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, legal proceedings relating to the defense may cause us to incur significant expenses and reduce our resources available for development activities.

If our trademarks are not adequately protected, we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks, CASCADIAN THERAPEUTICS and CASCADIAN, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to this trademark and build name recognition in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademark, then we may not be able to compete effectively and our business may be adversely affected.

If we are unable to obtain intellectual property rights to develop or market our products or we infringe on a third-party patent or other intellectual property rights, we may need to alter or terminate a product development program.

If our product candidates infringe or conflict with the rights of others, we may not be able to manufacture or market our product candidates, which could have a material and adverse effect on us.

While conducting clinical trials, we are exempt from patent infringement based on the Drug Price Competition and Patent Term Restoration Act or Hatch–Waxman Act, (codified in relevant part at 35 U.S.C. §271(e)), which provides an exemption for activities conducted in order to obtain FDA approval of a drug product. However, issued patents held by others may limit our ability to develop commercial products. All issued patents are entitled to a presumption of validity under the laws of the United States. If we need licenses to such patents to permit us to develop or market our product candidates, we may be required to pay significant fees or royalties, and we cannot be certain that we would be able to obtain such licenses on commercially reasonable terms, if at all. Competitors or third parties may obtain patents that may cover subject matter we use in developing the technology required to bring our product candidates to market.

We know that others have filed patent applications in various jurisdictions that relate to several areas in which we are developing products. Some of these patent applications have already resulted in the issuance of patents and some are still pending. We may be required to alter our processes or product candidates, pay licensing fees or cease activities.

If use of technology incorporated into or used to produce our product candidates is challenged, or if our processes or product candidates conflict with patent rights of others, third parties could bring legal actions against us, in the United States, Europe, and elsewhere, claiming damages and seeking to enjoin manufacturing and marketing of the affected products. Additionally, it is not possible to predict with certainty what patent claims may issue from pending applications. In the United States, for example, patent prosecution can proceed in secret prior to issuance of a patent. As a result, third parties may be able to obtain patents with claims relating to our product candidates or technology, which they could attempt to assert against us. Further, as we develop our products, third parties may assert that we infringe the patents currently held or licensed by them and it is difficult to predict the outcome of any such action. Ultimately, we could be prevented from commercializing a product, or forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights, which could have a material and adverse effect on our business, financial condition and results of operations.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights in, or to use, our technology.

There has been significant litigation in the biopharmaceutical industry over patents and other proprietary rights and if we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If these legal actions are successful, in addition to any potential liability for damages, we could be required to obtain a license, grant cross-licenses and pay substantial royalties in order to continue to manufacture or market the affected products.

The cost of litigation to uphold the validity of patents to prevent infringement or to otherwise protect our proprietary rights can be substantial. If the outcome of litigation is adverse to us, third parties may be able to use the challenged technologies without payment to us. There is also the risk that, even if the validity of a patent were upheld, a court would refuse to stop the other party from using the inventions, including because its activities do not infringe that patent. There is no assurance that we would prevail in any legal action or that any license required under a third-party patent would be made available on acceptable terms or at all. If any of these events were to occur, our business, financial condition and results of operations would be materially and adversely effected.

If any products we develop become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, our ability to successfully commercialize our products will be impaired.

Our future revenues, profitability and access to capital will be affected by the continuing efforts of governmental and private third-party payers to contain or reduce the costs of health care through various means. We expect a number of federal, state and foreign proposals to control the cost of drugs through government regulation. We are unsure of the impact that the potential repeal of recent health care reform legislation may have on our business or what actions federal, state, foreign and private payers may take or reforms that may be implemented in the future. Therefore, it is difficult to predict the effect of any potential reform on our business. Our ability to commercialize our products successfully will depend, in part, on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, such as Medicare and Medicaid in the United States, private health insurers and other organizations. Significant uncertainty exists as to the reimbursement status of newly approved health care products, particularly for indications for which there is no current effective treatment or for which medical care typically is not sought. Adequate third-party coverage may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product research and development. If adequate coverage and reimbursement levels are not provided by government and third-party payers for use of our products, our products may fail to achieve market acceptance without a substantial reduction in price or at all and our results of operations will be harmed.

Governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market our future products in both the United States and foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our product. In some foreign countries, particularly in the European Union, prescription drug pricing is subject to government control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug candidate. 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 future product to other available therapies.

Domestic and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare, including drugs. In the United States, there have been, and we expect that there will continue to be, federal and state proposals to implement similar governmental control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. While the current federal administration has indicated an intent to repeal the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, PPACA, the current administration has also indicated an intent to address prescription drug pricing and recent Congressional hearings have brought increased public attention to the costs of prescription drugs.

We anticipate that healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and downward pressure on the price for any approved product, and could seriously harm our prospects. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate which may limit its commercial potential.

The use of tucatinib or our other product candidates in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers, pharmaceutical companies or other third parties. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for approved products;
- delay in completing or failure to complete enrollment in any clinical trial of the affected product;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

Although we currently have product liability insurance coverage for our clinical trials for expenses or losses up to a $10 million aggregate annual limit, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any or all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to clinical trial or product liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for tucatinib or our other product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

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

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address cancer indications for which we are currently developing products or for which we may develop products in the future. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the design, development and commercialization of tucatinib and our other product candidates. We expect any product candidate that we commercialize on our own or with a collaboration partner will compete with existing, market-leading products and products in development. The following information provides a landscape view of known marketed products or programs in development that compete with our product candidates:

Tucatinib is an inhibitor of the receptor tyrosine kinase HER2, also known as ErbB2. There are multiple marketed products which target HER2, including the antibodies trastuzumab (Herceptin®) and pertuzumab (Perjeta®) and the antibody toxin conjugate ado-trastuzumab emtansine or T-DM1 (Kadcyla®). In addition, lapatinib (Tykerb®) is a dual EGFR/HER2 oral kinase inhibitor for the treatment of metastatic breast cancer and neratinib (Nerlynx®) is a EGFR/HER2/HER4 inhibitor indicated for extended adjuvant use that is also being studied for use in metastatic breast cancer. Margetuximab is a HER2 targeted, Fc-optimized antibody which is in late-stage clinical development.

With respect to CASC-578 and CASC-674, there are multiple competing product candidates in clinical trials and preclinical development.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to:

- design and develop product candidates that are superior to other products in the market;
- attract qualified scientific, medical, sales and marketing and commercial personnel;
- obtain patent and/or other proprietary protection for our processes and product candidates;
- obtain required regulatory approvals; and
- successfully collaborate with others, as needed, in the design, development and commercialization of our product candidates.

In addition, established competitors may invest significant resources to quickly discover and develop novel compounds that could make tucatinib or our other product candidates obsolete. In addition, any new product that competes with a generic market-leading product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome severe price competition and to be commercially successful. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer.

If we are unable to enter into agreements with partners to perform sales and marketing functions, or build these functions ourselves, we will not be able to commercialize our product candidates.

We currently do not have any internal sales, marketing or distribution capabilities. In order to commercialize tucatinib or any of our other product candidates, we must either acquire or internally develop a selling, marketing and distribution infrastructure or enter into agreements with partners to perform these services for us. We may not be able to enter into such arrangements on commercially acceptable terms, if at all. Factors that may inhibit our efforts to commercialize our product candidates without entering into arrangements with third parties include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating a sales and marketing organization.

If we are not able to partner with a third party and are not successful in recruiting sales and marketing personnel or in building a sales and marketing and distribution infrastructure, we will have difficulty commercializing tucatinib or any of our other product candidates, which would adversely affect our business and financial condition. The complexity of regulations regarding the sales and marketing of pharmaceutical products may require costly and time-consuming efforts to train any sales and marketing personnel, which would negatively impact our financial condition and business operations.

If we lose key personnel, or we are unable to attract and retain highly-qualified personnel on a cost-effective basis, it will be more difficult for us to manage our existing business operations and to identify and pursue new growth opportunities.

Our success depends in large part upon our ability to attract and retain highly qualified scientific, clinical, manufacturing, and management personnel. In addition, future growth will require us to continue to implement and improve our managerial, operational and financial systems, and continue to retain, recruit and train additional qualified personnel, which may impose a strain on our administrative and operational infrastructure. Any difficulties in hiring or retaining key personnel or managing this growth could disrupt our operations. The competition for qualified personnel in the biopharmaceutical field is strong. We are highly dependent on our continued ability to attract, retain and motivate highly-qualified management, clinical and scientific personnel. Due to our limited resources, and the strong competition for qualified personnel, we may not be able to effectively recruit, train and retain additional qualified personnel. If we are unable to retain key personnel or manage our growth effectively, we may not be able to implement our business plan.

Furthermore, we have not entered into non-competition agreements with all of our key employees and we do not maintain "key person" life insurance on any of our officers, employees or consultants. The loss of the services of existing personnel, the failure to recruit additional key scientific, technical and managerial personnel in a timely manner, and the loss of our employees to our competitors would each harm our research, development and clinical programs and our business.

Our business is subject to complex environmental legislation that increases both our costs and the risk of noncompliance.

Our business involves the use of hazardous material, which requires us to comply with environmental regulations and we will be required to adjust to new and upcoming requirements relating to the materials composition of our product candidates. If we use hazardous materials in a manner that causes contamination or injury or violates laws, we may be liable for damages. Environmental regulations could have a material adverse effect on the results of our operations and our financial position. We maintain insurance for any liability associated with our hazardous materials activities, and it is possible in the future that our coverage would be insufficient if we incurred a material environmental liability.

If we fail to establish and maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired, which would adversely affect our consolidated operating results, our ability to operate our business, and our stock price, and could result in litigation or similar actions.

Ensuring that we have adequate internal financial and accounting controls and procedures in place to produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Failure on our part to have effective internal financial and accounting controls would cause our financial reporting to be unreliable, could have a material adverse effect on our business, operating results, and financial condition, and could cause the trading price of our common stock to fall dramatically. Our management is responsible for establishing and maintaining adequate internal control over financial reporting to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our management does not believe that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the company will be detected.

We cannot be certain that the actions we have taken to ensure we have adequate internal controls over financial reporting will be sufficient. In future periods, if the process required by Section 404 of the Sarbanes-Oxley Act reveals any material weaknesses or significant deficiencies, the correction of any such material weaknesses or significant deficiencies could require remedial measures which could be costly and time-consuming. In addition, in such a case, we may be unable to produce accurate financial statements on a timely basis. Any associated accounting restatement could create a significant strain on our internal resources and cause delays in our release of quarterly or annual financial results and the filing of related reports, increase our costs and cause management distraction. Any of the foregoing could cause investors to lose confidence in the reliability of our consolidated financial statements, which could cause the market price of our common stock to decline and make it more difficult for us to finance our operations and growth.

We may face risks related to securities litigation that could result in significant legal expenses and settlement or damage awards.

We have in the past been, and may in the future become, subject to claims and litigation alleging violations of the securities laws or other related claims, which could harm our business and require us to incur significant costs. We are generally obliged, to the extent permitted by law, to indemnify our current and former directors and officers who are named as defendants in these types of lawsuits. Any future litigation may require significant attention from management and could result in significant legal expenses, settlement costs or damage awards that could have a material impact on our financial position, results of operations, and cash flows.

Risks Related to the Ownership of Our Common Stock

The trading price of our common stock may be volatile.

The market prices for and trading volumes of securities of biopharmaceutical companies, including our securities, have been historically volatile. For example, we experienced significant volatility following a press release regarding our Phase 1b studies of tucatinib in December 2015. The market has from time to time experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. The market price of our common shares may fluctuate significantly due to a variety of factors, including:

- the results of preclinical testing and clinical trials by us, our competitors and/or companies that are developing products that are similar to ours (regardless of whether such products are potentially competitive with ours);
- public concern as to the safety of products developed by us or others;
- our ability to timely enroll patients and complete our pivotal HER2CLIMB clinical study;
- the results of the HER2CLIMB study or other studies of tucatinib that we or clinical investigators may undertake;
- our ability to execute our business strategies;
- technological innovations or new therapeutic products;
- governmental regulations;
- developments in patent or other proprietary rights;
- litigation;
- general market conditions in our industry or in the economy as a whole;
- comments by securities analysts;
- comments made on social media platforms, including blogs, websites, message boards and other forms of Internet-based communications;
- difficulty with the market interpreting and understanding complex data;
- the issuance of additional shares of common stock, or securities convertible into, or exercisable or exchangeable for, shares of our common stock in connection with financings, acquisitions or otherwise;
- the incurrence of debt; and
- political instability, natural disasters, war and/or events of terrorism.

We may seek to raise additional capital in the future; however, such capital may not be available to us on reasonable terms, if at all, when or as we require additional funding. If we issue additional shares of our common stock or other securities that may be convertible into, or exercisable or exchangeable for, our common stock, our existing stockholders would experience further dilution.

We expect that we will seek to raise additional capital from time to time in the future. For example, in January 2017 we sold 26,659,300 shares of our common stock and 1,818 shares of our Series E preferred stock in concurrent but separate public offerings.

Future financings may involve the issuance of debt, equity and/or securities convertible into or exercisable or exchangeable for our equity securities. These financings may not be available to us on reasonable terms or at all when and as we require funding. In addition, we may need to increase our authorized capital to ensure that we have shares of common stock available for issuance in any future equity financings. An increase in our authorized capital will require approval of a majority of our stockholders and we may not be able to obtain that approval. If we are able to consummate financings, the trading price of our common stock could be adversely affected and/or the terms of such financings may adversely affect the interests of our existing stockholders. Any failure to obtain additional working capital when required would have a material adverse effect on our business and financial condition and would be expected to result in a decline in our stock price. Any issuances of our common stock, preferred stock, or securities such as warrants or notes that are convertible into, exercisable or exchangeable for, our capital stock, would have a dilutive effect on the voting and economic interest of our existing stockholders.

Several stockholders own a significant percentage of our outstanding capital stock and will be able to influence stockholder and management decisions, which may conflict with your interests as a stockholder.

As of September 30, 2017, New Enterprise Associates and its affiliates (NEA), Baupost, Inc., Redmile Group, LLC (Redmile) and Biotechnology Value Fund and its affiliates (BVF) collectively held combined voting power over approximately 49% of the outstanding shares of our common stock, based on the Schedules 13D and 13G filed by them with the Securities and Exchange Commission. Additionally, NEA holds shares of our preferred stock convertible into up to 1,818,000 additional shares of our common stock and BVF holds shares of our preferred stock convertible into up to 5,430,601 additional shares of our common stock. As a result of their respective ownership positions, NEA, Baupost, Redmile and BVF each may have the ability to significantly influence matters requiring stockholder approval, including, without limitation, the election or removal of directors, an increase in our authorized common stock, mergers, acquisitions, changes of control of our company and sales of all or substantially all of our assets. As a result, of this concentration of ownership, these stockholders may have a significant influence in our management and affairs. This influence may delay, deter or prevent acts that may be favored by our other stockholders, as the interests of these stockholders may not always coincide with the interests of our other stockholders. In addition, this concentration of share ownership may adversely affect the trading price of our shares because it may limit the trading volume and purchase demand for outstanding shares, could adversely affect our stock price should any of these stockholders elect to sell some or all of their shares, and investors may perceive disadvantages in owning shares in a company with significant stockholders.

Because we do not expect to pay dividends on our common stock, stockholders will benefit from an investment in our common stock only if it appreciates in value.

We have never paid cash dividends on our common shares and have no present intention to pay any dividends in the future. We are not profitable and do not expect to earn any material revenues for at least several years, if at all. As a result, we intend to use all available cash and liquid assets in the development of our business. Any future determination about the payment of dividends will be made at the discretion of our board of directors and will depend upon our earnings, if any, capital requirements, operating and financial conditions and on such other factors as our board of directors deems relevant. As a result, the success of an investment in our common stock will depend upon any future appreciation in its value. There is no guarantee that our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

We can issue shares of preferred stock that may adversely affect the rights of a stockholder of our common stock.

Our certificate of incorporation authorizes us to issue up to 10,000,000 shares of preferred stock with designations, rights, and preferences determined from time-to-time by our board of directors. Accordingly, our board of directors is empowered, without stockholder approval, to issue preferred stock with dividend, liquidation, conversion, voting or other rights superior to those of holders of our common stock. For example, an issuance of shares of preferred stock could:

- adversely affect the voting power of the holders of our common stock;
- make it more difficult for a third party to gain control of us;
- discourage bids for our common stock at a premium;
- limit or eliminate any payments that the holders of our common stock could expect to receive upon our liquidation; or
- otherwise adversely affect the market price or our common stock.

We have in the past issued, and we may at any time in the future issue, additional shares of authorized preferred stock. As of September 30, 2017, we had outstanding preferred stock convertible into 7,248,601 shares of common stock. If the holders of such shares of preferred stock convert their shares into common stock, existing holders of our common stock will experience dilution.

Our management has broad discretion over the use of proceeds from the sale of shares of our common and preferred stock and may not use such proceeds in ways that increase the value of our stock price.

In our June 2016 public offering, we sold 6,708,333 shares of common stock and 17,250 shares of Series D convertible preferred stock for net proceeds of approximately $43.3 million and in our January 2017 public offering, we sold 26,659,300 shares of our common stock and 1,818 shares of our Series E convertible preferred stock in concurrent but separate public offerings for net proceeds of approximately $88.0 million. We have broad discretion over the use of proceeds from the sale of these shares, and we could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of tucatinib and our other product candidates and cause the price of our common stock to decline.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit No.	Exhibit Description	Incorporated by Reference			Filed/ Furnished Herewith
		Form	Exhibit No.	Filing Date	
31.1	Rule 13a-14(a) / 15d-14(a) Certification of the Principal Executive Officer.				X
31.2	Rule 13a-14(a) / 15d-14(a) Certification of the Principal Financial Officer.				X
32.1*	Section 1350 Certification of the Principal Executive Officer.				X
32.2*	Section 1350 Certification of the Principal Financial Officer.				X
101.INS	XBRL Instance Document.				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				X

* This certification is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, or Exchange Act, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or Securities Act, or the Exchange Act, irrespective of any general incorporation language contained in such filing.

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.

CASCADIAN THERAPEUTICS, INC.

Date: November 8, 2017

/s/ Scott D. Myers

Scott D. Myers,
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2017

/s/ Julia M. Eastland

Julia M. Eastland
Chief Financial Officer, Chief Business Officer and Secretary
(Principal Financial and Accounting Officer)

EXHIBIT 31.1

CERTIFICATION

I, Scott D. Myers, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cascadian Therapeutics, Inc., (the "Registrant");

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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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 fiscal 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 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.

November 8, 2017

/s/ Scott D. Myers
Scott D. Myers,
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Julia M. Eastland, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Cascadian Therapeutics, Inc., (the "Registrant");

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 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the Registrant and 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) 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

(d) 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 fiscal 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 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.

November 8, 2017

/s/ Julia M. Eastland
Julia M. Eastland,
Chief Financial Officer, Chief Business Officer and Secretary
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

I, Scott D. Myers, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Cascadian Therapeutics, Inc. for the quarterly period ended September 30, 2017, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Cascadian Therapeutics, Inc.

November 8, 2017

/s/ Scott D. Myers
Scott D. Myers
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002
(18 U.S.C. SECTION 1350)

I, Julia M. Eastland, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report on Form 10-Q of Cascadian Therapeutics, Inc. for the quarterly period ended September 30, 2017, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Quarterly Report on Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of Cascadian Therapeutics, Inc.

November 8, 2017

/s/ Julia M. Eastland
Julia M. Eastland
Chief Financial Officer, Chief Business Officer and Secretary
(Principal Financial and Accounting Officer)