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

FORM 10-Q

☒ **Quarterly Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 2016

OR

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from _____ to _____.

Commission File Number: 001-37490

ProNAi Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**20-0138994**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

ProNAi Therapeutics, Inc.
2150 – 885 West Georgia Street
Vancouver, British Columbia, Canada V6C 3E8
(Address of principal executive offices and zip code)

(604) 558-6536
(Registrant's telephone number, including area code)

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

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	☐

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

As of November 8, 2016, there were 30,366,919 shares of the Registrant's Common Stock, $0.001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act), and section 27A of the Securities Act of 1933, as amended (Securities Act). All statements other than statements of historical fact are “forward-looking statements” for purposes of this Quarterly Report on Form 10-Q. These forward-looking statements may include, but are not limited to, statements regarding our future clinical development activities, expected timing and results of clinical trials, future results of operations and financial position, our business strategy and plans and our objectives for future operations. The words “believe,” “may,” “will,” “potentially,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “plan” “expect,” and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements to conform these statements to actual results or to changes in our expectations, except as required by law.

As used in this Quarterly Report on Form 10-Q, the terms “ProNAi,” “the Company,” “we,” “us,” and “our” refer to ProNAi Therapeutics, Inc., a Delaware corporation, and its subsidiaries taken as a whole, unless otherwise noted. ProNAi and DNAi are our registered trademarks. The “ProNAi” logo and all product names are our common law trademarks.

PART I

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

PRONAI THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(unaudited)
(in thousands, except share and per share data)

	September 30, 2016	December 31, 2015
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents (Note 5)	$ 122,682	$ 150,180
Prepaid expenses and other current assets (Note 5)	1,822	1,673
Total current assets	124,504	151,853
Property and equipment, net (Note 5)	357	566
Other assets	205	349
TOTAL ASSETS	$ 125,066	$ 152,768
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accrued liabilities (Note 5)	$ 13,958	$ 7,016
Accounts payable	174	358
Other current liabilities	—	23
Total current liabilities	14,132	7,397
TOTAL LIABILITIES	14,132	7,397
Commitments and Contingencies (Note 6)		
STOCKHOLDERS' EQUITY (DEFICIT):		
Preferred stock, $0.001 par value; 10,000,000 shares authorized as of September 30, 2016 and December 31, 2015; nil shares issued and outstanding as of September 30, 2016 and December 31, 2015	—	—
Common stock, $0.001 par value; 500,000,000 shares authorized as of September 30, 2016 and December 31, 2015; 30,350,560 and 30,058,105 shares issued and outstanding as of September 30, 2016 and December 31, 2015	30	30
Additional paid-in capital	683,710	679,528
Accumulated deficit	(572,806)	(534,187)
TOTAL STOCKHOLDERS' EQUITY	110,934	145,371
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 125,066	$ 152,768

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

PRONAI THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	$ 12,323	$ 8,295	$ 28,074	$ 18,329
General and administrative	2,960	2,738	10,768	6,053
Total operating expenses	15,283	11,033	38,842	24,382
Loss from operations	(15,283)	(11,033)	(38,842)	(24,382)
Other income (expense), net:				
Change in fair value of preferred stock warrants	—	(7,487)	—	(17,443)
Other income	88	29	259	48
Total other income (expense), net	88	(7,458)	259	(17,395)
Loss before provision for income taxes	(15,195)	(18,491)	(38,583)	(41,777)
Provision for income taxes	14	14	36	25
Net loss	(15,209)	(18,505)	(38,619)	(41,802)
Adjustment to redemption value on redeemable convertible preferred stock	—	(222,130)	—	(374,015)
Series B and B-1 redeemable convertible preferred stock dividend	—	(5,543)	—	(5,543)
Series C and D redeemable convertible preferred stock dividend	—	(20,366)	—	(20,366)
Net loss attributable to common stockholders	$ (15,209)	$ (266,544)	$ (38,619)	$ (441,726)
Net loss per share attributable to common stockholders, basic and diluted (Note 3)	$ (0.50)	$ (11.03)	$ (1.28)	$ (48.36)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted (Note 3)	30,331,616	24,167,238	30,198,134	9,133,978

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

PRONAI THERAPEUTICS, INC.

Condensed Consolidated Statements of Convertible and Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(unaudited)
(in thousands, except share and per share data)

	Convertible Preferred Stock		Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance—December 31, 2014	224,564	$$2,543	17,042,064	$ 141,832	1,588,701	$ 2	$ —	$ (10)	$ (107,807)	$ (107,815)
Issuance of common stock for exercise of stock options	—	—	—	—	41,505	—	18	—	—	18
Stock-based compensation	—	—	—	—	—	—	3,186	—	—	3,186
Vesting of early exercised stock options	—	—	—	—	—	—	90	—	—	90
Issuance of redeemable convertible preferred stock upon exercise of redeemable convertible preferred stock warrants	—	—	481,671	8,976	—	—	—	—	—	—
Issuance of redeemable convertible preferred stock upon net exercise of redeemable convertible preferred stock warrants upon initial public offering	—	—	390,032	11,785	—	—	—	—	—	—
Adjustment to redemption value on redeemable convertible preferred stock	—	—	—	374,015	—	—	(895)	—	(373,120)	(374,015)
Conversion of convertible preferred stock to common stock upon initial public offering	(224,564)	(2,543)	—	—	252,817	—	2,543	—	—	2,543
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	—	—	(17,913,767)	(536,608)	18,109,136	18	536,590	—	—	536,608
Issuance of common stock in connection with initial public offering, net of issuance costs of $14.8 million	—	—	—	—	9,315,000	9	143,540	—	—	143,549
Series B and B-1 redeemable convertible preferred stock dividend	—	—	—	—	—	—	(5,543)	—	—	(5,543)
Series C and D redeemable	—	—	—	—	750,946	1	(1)	—	—	—

convertible preferred stock dividend										
Reclassification of other-than-temporary losses on short-term investments to net loss	—	—	—	—	—	—	—	10	—	10
Net loss	—	—	—	—	—	—	—	—	(53,260)	(53,260)

	Convertible Preferred Stock		Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance—December 31, 2015	—	—	—	—	30,058,105	30	679,528	—	(534,187)	145,371
Issuance of common stock for exercise of stock options	—	—	—	—	292,455	—	194	—	—	194
Stock-based compensation	—	—	—	—	—	—	3,965	—	—	3,965
Vesting of early exercised stock options	—	—	—	—	—	—	23	—	—	23
Net loss	—	—	—	—	—	—	—	—	(38,619)	(38,619)
Balance—September 30, 2016	—	$ —	—	$ —	30,350,560	$ 30	$683,710	$ —	$ (572,806)	$ 110,934

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

PRONAI THERAPEUTICS, INC.

Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (38,619)	$ (41,802)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	3,965	1,912
Change in fair value of preferred stock warrant liabilities	—	17,443
Depreciation and amortization	151	71
Non-cash restructuring charges (note 12)	811	—
Other	36	1
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(843)	(694)
Accrued liabilities	7,184	1,397
Accounts payable	(184)	483
Net cash used in operating activities	(27,499)	(21,189)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(196)	(381)
Change in restricted cash	25	(150)
Proceeds from sale of property and equipment	43	—
Purchase of short-term investments	—	(21)
Proceeds from sale of short-term investments	—	10,031
Net cash (used in) provided by investing activities	(128)	9,479
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of common stock options	194	18
Payment of deferred offering costs	(15)	(3,389)
Proceeds from issuance of common stock upon initial public offering, net of issuance costs	—	147,270
Payment of Series B and B-1 redeemable convertible preferred stock cumulative dividend	—	(5,543)
Proceeds from early exercise of stock options	—	13
Proceeds from exercise of redeemable convertible preferred stock warrants	—	1,507
Net cash provided by financing activities	179	139,876
Effect of foreign exchange rate changes on cash and cash equivalents	(50)	(12)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(27,498)	128,154
CASH AND CASH EQUIVALENTS — Beginning of period	150,180	29,154
CASH AND CASH EQUIVALENTS — End of period	$122,682	$ 157,308
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid for income taxes	$ 94	$ 8
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING INFORMATION:		
Change in redemption value of redeemable convertible preferred stock	$ —	$(374,015)
Fair value of common stock issued in settlement of Series C and Series D redeemable convertible preferred stock cumulative dividends	$ —	$ 20,366
Conversion of preferred stock to common stock	$ —	$ 539,151
Issuance of redeemable convertible preferred stock on exercise of warrants	$ —	$ 19,253
Property and equipment purchases included in accounts payable and accrued liabilities	$ 10	$ 80

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

PRONAI THERAPEUTICS, INC.

Notes to Condensed Consolidated Financial Statements
(unaudited)

1. The Company and Basis of Presentation

Organization and Description of Business

ProNAi Therapeutics, Inc. (together with its subsidiaries, collectively referred to as the "Company"), a Delaware corporation, is a clinical-stage drug development company focused on advancing targeted therapeutics for the treatment of patients with cancer. The Company is managed by a world-class team with a proven track record of success in oncology drug development. ProNAi is building a broad and diverse pipeline of promising oncology assets against emerging targets on the leading edge of cancer biology. ProNAi's lead drug candidate is PNT737, a highly selective, orally bioavailable small molecule inhibitor of Checkpoint kinase 1 (Chk1), a central regulator of the DNA Damage Response (DDR) network. ProNAi is also advancing PNT141, a highly selective, orally bioavailable small molecule inhibitor of cell division cycle 7 kinase (Cdc7).

The Company's primary activities since inception have been conducting research and development activities, conducting preclinical and clinical testing, recruiting personnel, performing business and financial planning, identifying and evaluating additional drug candidates for potential in-licensing or acquisition, and raising capital to support development activities.

The Company has not generated any product revenue related to its primary business purpose to date, nor has it generated any income, and is subject to a number of risks and uncertainties, which include dependence on key individuals, the need to identify and successfully develop commercially viable products, the need to obtain regulatory approval for its products and commercialize them, and the need to obtain adequate additional financing to fund the development of its product candidates.

Initial Public Offering

On July 15, 2015, the Company's Registration Statement on Form S-1 (File No. 333-204921) relating to the initial public offering (IPO) of its common stock was declared effective by the Securities and Exchange Commission (SEC). Pursuant to such Registration Statement, the Company sold an aggregate of 9,315,000 shares of its common stock at a price of $17.00 per share for aggregate cash proceeds of approximately $143.6 million, net of underwriting discounts and commissions and offering costs.

On July 21, 2015, immediately prior to the closing of the IPO, all outstanding shares of convertible and redeemable convertible preferred stock converted into 18,361,953 shares of common stock, including an aggregate of 390,680 shares of common stock that were issued pursuant to the net exercise of 493,648 preferred stock warrants at the IPO price of $17.00 per share and an aggregate of 481,671 shares of common stock that were issued pursuant to the cash exercise of 481,671 preferred stock warrants. The IPO closed on July 21, 2015.

As discussed further in Note 8, on the closing of the IPO, the Company paid $5.5 million to the holders of its Series B and B-1 redeemable convertible preferred stock in settlement of the cumulative dividends. In addition, the Company issued 750,946 shares of common stock to the holders of its Series C and D redeemable convertible preferred stock in settlement of the cumulative dividends.

Following the filing of the Restated Certificate of Incorporation of the Company on July 21, 2015, the number of shares of capital stock the Company is authorized to issue is 510,000,000 shares, of which 500,000,000 shares may be common stock and 10,000,000 shares may be preferred stock. Both the common stock and the preferred stock have a par value of $0.001 per share.

Reverse Stock Split

On June 29, 2015, the Company's board of directors approved an amendment to the Company's Amended and Restated Certificate of Incorporation to effect a reverse split of the Company's common stock, convertible preferred stock and redeemable convertible preferred stock at a 7.45-to-1 ratio (Reverse Stock Split). The Reverse Stock Split became effective on July 2, 2015, upon the filing of the amendment to the Company's Amended and Restated Certificate of Incorporation. The authorized shares and par value of the common, convertible preferred and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. All issued and outstanding common stock, convertible preferred stock, redeemable convertible preferred stock, warrants to purchase preferred stock, options to purchase common stock and per share amounts contained in the condensed consolidated financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.

2. Summary of Significant Accounting Policies

Basis of Presentation

The condensed consolidated balance sheet as of September 30, 2016, the condensed consolidated statements of operations for the three and nine months ended September 30, 2016 and 2015, the condensed consolidated statements of cash flows for the nine months ended September 30, 2016 and 2015, and the condensed consolidated statements of convertible and redeemable convertible preferred stock and stockholders' equity (deficit) as of September 30, 2016 are unaudited. The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair presentation of the Company's condensed consolidated financial statements included in this report. The condensed consolidated financial data disclosed in these notes to the condensed consolidated financial statements related to the three and nine month periods are also unaudited. The condensed consolidated results of operations for the three and nine months ended September 30, 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016, or for any other future annual or interim period. The consolidated balance sheet as of December 31, 2015 included herein was derived from the audited consolidated financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2015, filed with the SEC on March 3, 2016.

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the reported amounts of expense during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include, but are not limited to the fair value of stock options, accruals such as research and development costs, the fair value of common stock, the fair value of preferred stock, the fair value of preferred stock warrant liabilities, and recoverability of the Company's net deferred tax assets and related valuation allowance. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could materially differ from those estimates.

Foreign Currency

The functional currency of the Company's foreign subsidiaries is the U.S. Dollar. Transactions denominated in currencies other than the functional currency are remeasured to the functional currency at the average exchange rate in effect during the period. At the end of each reporting period, monetary assets and liabilities are remeasured to the functional currency using exchange rates in effect at the balance sheet date. Non-monetary assets and liabilities are recorded at historical exchange rates. Gains and losses related to remeasurement are recorded in other income (expense) in the condensed consolidated statements of operations. The net foreign exchange transaction gains (losses) included in other income (expense) in the accompanying condensed consolidated statements of operations was insignificant for the three and nine months ended September 30, 2016 and 2015.

Cash and Cash Equivalents

The Company considers all highly liquid investments with an original maturity of three months or less from the date of purchase to be cash equivalents. Cash and cash equivalents consist primarily of funds invested in readily available checking and savings accounts and highly liquid investments in money market funds.

Restricted Cash

Restricted cash represents collateral for a corporate credit card facility and security deposits required for facility leases. Restricted cash consists of funds invested in a money market fund. As of September 30, 2016, the current portion of restricted cash of $12,000 was included in prepaid expenses and other current assets and the long-term portion of restricted cash of $0.2 million was included in other assets in the accompanying condensed consolidated balance sheets. As of December 31, 2015, the current portion of restricted cash included in prepaid expenses and other current assets and the long-term portion of restricted cash included in other assets were $25,000 and $0.2 million, respectively.

Concentrations of Credit Risk

Financial instruments that subject the Company to significant concentrations of credit risk consist of cash, cash equivalents and restricted cash. All of the Company's cash, cash equivalents and restricted cash are held at financial institutions in the United States and Canada that management believes to be of high credit quality. Deposits held in the United States with these financial institutions exceed federally insured limits.

The primary focus of the Company's investment strategy is to preserve capital and meet liquidity requirements. The Company's investment policy addresses the level of credit exposure by limiting the concentration in any one corporate issuer and establishing a minimum allowable credit rating.

Comprehensive Loss

The Company had no components of comprehensive loss other than net loss for all periods presented.

Fair Value of Financial Instruments

The Company's cash and cash equivalents, restricted cash, other current assets, accounts payable, and accrued liabilities approximate their fair value at September 30, 2016 and December 31, 2015, due to their short duration. The Company's preferred stock warrant liabilities contain unobservable inputs that reflect the Company's own assumptions in which there is little, if any, market activity at the measurement date; thus, the Company's warrant liabilities were measured at fair value on a recurring basis using unobservable inputs until they were exercised in 2015.

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines the fair value of its financial instruments based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

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

Level 2 – Inputs are observable, unadjusted quoted prices in active markets for similar assets or liabilities, unadjusted quoted prices for identical or similar assets or liabilities 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 related assets or liabilities; and

Level 3 – Unobservable inputs that are significant to the measurement of the fair value of the assets or liabilities that are supported by little or no market data.

Property and Equipment, Net

Property and equipment, net are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization on property and equipment, excluding leasehold improvements, is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Depreciation and amortization begins at the time the asset is placed in service. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the condensed consolidated balance sheet and the resulting gain or loss is reflected in the condensed consolidated statement of operations. Leasehold improvements are amortized on a straight-line basis over the shorter of the estimated useful lives of the assets or the remaining lease term.

Other Assets

Other assets consist primarily of restricted cash pledged as collateral for a corporate credit card facility and security deposits required for facility leases.

Preferred Stock Warrant Liabilities

The Company accounted for its warrants issued in connection with its various financing transactions based upon the characteristics and provisions of the instrument. Warrants classified as derivative liabilities were recorded on the Company's condensed consolidated balance sheets at their fair value on the date of issuance and remeasured to fair value on each subsequent reporting period, with the changes in fair value recognized as a component of other income (expense), net in the accompanying condensed consolidated statements of operations. On the closing of the IPO on July 21, 2015 (discussed in Note 1), all outstanding warrants were exercised and the liability on the preferred stock warrants was reclassified to additional paid-in capital in stockholders' equity (deficit), and was no longer subject to remeasurement.

Research and Development Costs

Research and development costs are expensed as incurred. The Company accounts for non-refundable advance payments for goods and services that will be used in future research and development activities as expenses when the goods have been received or when the service has been performed rather than when the payment is made. Depending on the timing of payments to service providers of research and development costs, the Company recognizes prepaid expenses or accrued expenses related to these costs. These prepaid or accrued expenses are based on management's estimates of the work performed under service agreements and milestones achieved. In the event that a clinical trial is terminated early, the Company records an accrual for the estimated remaining costs to complete the trial in the period of termination.

Upfront payments made in connection with license agreements are expensed as research and developments costs, as the assets acquired do not have alterative future use. Contingent milestone payment obligations due to third parties under license agreements are expensed when the milestones are considered probable of occurring.

Research and development costs include fees incurred in connection with license agreements, compensation and other related costs for employees engaged in research and development, costs associated with preclinical studies and trials, regulatory activities, manufacturing activities to support clinical activities, license fees, fees paid to external service providers that conduct certain research and development, clinical, and manufacturing activities on behalf of the Company and an allocation of overhead expenses.

Stock-Based Compensation

The Company accounts for share-based payments at fair value, which is measured using the Black-Scholes option-pricing model. For share-based awards that vest subject to the satisfaction of a service requirement, the fair value measurement date for employee stock-based compensation awards is the date of grant and the expense is recognized on a straight-line basis over the vesting period.

For share-based awards that vest subject to the satisfaction of a service requirement and a performance component, the fair value measurement date is the date of grant and is recognized over the requisite service period as achievement of the performance objective becomes probable.

Stock-based compensation arrangements with non-employees are recognized at the grant date and remeasured to fair value at each reporting period. The expense is recognized over the vesting period, which is generally the service period.

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and the tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and the recorded cumulative net losses in prior fiscal periods, the net U.S. deferred tax assets have been offset by a full valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. The Company recognizes interest and penalties related to the underpayment of income taxes as a component of provision for income taxes.

Segment Information

Operating segments are components of an enterprise for which separate financial information is available and is evaluated regularly by the Company's chief operating decision maker in deciding how to allocate resources and assessing performance. The Company's chief operating decision maker is its Chief Executive Officer.

The Company's Chief Executive Officer views the Company's operations and manages its business in one operating segment, which is the business of researching, developing and commercializing therapies for the treatment of patients with cancer. Accordingly, the Company has a single reporting segment.

Recent Accounting Pronouncements Not Yet Effective

In February 2016, the Financial Accounting Standards Board (FASB) issued FASB Accounting Standards Update (ASU) No. 2016-02, *Leases (Topic 842)*. The amendments in this update require that organizations recognize lease assets and lease liabilities on the balance sheet and disclose key information about leasing arrangements. This ASU is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with early adoption permitted. The Company is currently assessing the impact of the ASU on the Company's consolidated financial statements.

In March 2016, the FASB issued FASB ASU No. 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The amendments in this update involve the simplification of several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. This ASU is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. The Company is currently assessing the impact of the ASU on the Company's consolidated financial statements.

3. Net Loss Per Share

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period, less common stock issued that is subject to repurchase, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing net loss by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, preferred stock and warrants to purchase preferred stock, stock options and common stock subject to repurchase are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following outstanding shares of common stock equivalents were excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been antidilutive:

	As of September 30,	
	2016	2015
Options to purchase common stock	6,629,163	3,314,159
Common stock subject to repurchase	—	39,493
Total potential dilutive shares	6,629,163	3,353,652

4. Fair Value Measurements

The Company measures and reports its cash equivalents and restricted cash at fair value. The following table sets forth the fair value of the Company's financial assets and liabilities measured on a recurring basis by level within the fair value hierarchy:

	September 30, 2016			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Financial Assets				
Money market funds	$120,962	$ —	$ —	$120,962
Restricted money market funds	200	—	—	200
Total financial assets	$121,162	$ —	$ —	$121,162

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Financial Assets				
Money market funds	$148,604	$ —	$ —	$148,604
Restricted money market funds	225	—	—	225
Total financial assets	$148,829	$ —	$ —	$148,829

Money market funds and restricted money market funds are measured at fair value on a recurring basis using quoted prices and are classified as a Level 1 input.

There were no transfers between Levels 1, 2 or 3 during the three and nine months ended September 30, 2016.

5. Balance Sheet Components

Cash and Cash Equivalents

Cash and cash equivalents consist of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Cash	$ 1,720	$ 1,576
Cash equivalents:		
Money market accounts	120,962	148,604
Total cash and cash equivalents	$ 122,682	$ 150,180

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Prepaid research and development project costs	$ 184	$ 878
Prepaid insurance	774	480
Other receivables	453	44
Other	411	271
Total prepaid expenses and other current assets	$ 1,822	$ 1,673

Property and Equipment, net

Property and equipment, net consists of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Computer equipment	$ 258	$ 242
Software	151	126
Lab equipment	—	236
Leasehold improvements	110	79
Furniture and fixtures	47	5
Property and equipment, gross	566	688
Less: accumulated depreciation	(209)	(122)
Total property and equipment, net	$ 357	$ 566

Depreciation and amortization related to the Company's property and equipment was $45,000 and $0.2 million for the three and nine months ended September 30, 2016 and was $32,000 and $0.1 million for the three and nine months ended September 30, 2015.

During the nine months ended September 30, 2016, as a result of the decision to halt investment in PNT2258 and the DNAi platform, the Company recorded impairment charges of $0.1 million on its lab equipment (note 12).

Accrued Liabilities

Accrued liabilities consist of the following:

	September 30, 2016	December 31, 2015
	(in thousands)	
Accrued license fee (note 6)	$ 9,000	$ —
Accrued employee-related costs	1,698	1,529
Accrued restructuring costs (note 12)	1,475	—
Accrued research and development costs	1,282	4,318
Accrued professional fees	324	933
Other	179	236
Total accrued liabilities	$ 13,958	$ 7,016

6. Commitments and Contingencies

License Agreements

In September 2016, the Company entered into an exclusive license agreement with CRT Pioneer Fund LP (CPF) for worldwide rights, know-how and materials to develop PNT737, a small molecule inhibitor targeting Chk1, a promising therapeutic target to treat cancer. Pursuant to the agreement, the Company is required to make a one-time upfront payment of $7.0 million to CPF. The Company will also pay CPF up to $2.0 million upon the successful transfer of two ongoing Phase I clinical trials. Additional milestone payments of up to an aggregate of $319.5 million may become payable to CPF upon the achievement of certain developmental, regulatory and commercial milestones. In addition, the Company is required to pay CPF, on a product-by-product and country-by-country basis, tiered high single-digit to low double-digit royalties on the net sales of any product successfully developed.

As of September 30, 2016, the Company has accrued the $7.0 million upfront payment, that was subsequently paid in October 2016, and the $2.0 million fee that will be due to CPF upon the successful transfer of two ongoing clinical trials. The related expense is included in research and development for the three and nine months ended September 30, 2016 in the accompanying condensed consolidated statements of operations. Additional milestone payments will be accrued once they are considered probable of occurring.

In May 2016, the Company entered into an exclusive license agreement (Carna License Agreement) with Carna Biosciences, Inc. (Carna) for worldwide rights to develop and commercialize PNT141, a small molecule kinase inhibitor targeting Cdc7. In exchange for this exclusive right, the Company paid Carna an upfront payment of $0.9 million in June 2016. The Company will be required to pay Carna milestone payments of up to an aggregate of $270.0 million upon achievement of certain developmental, regulatory and commercial milestone events. In addition, for product candidates defined under the Carna License Agreement, the Company is required to pay Carna tiered single-digit royalties on net sales.

As of September 30, 2016, the Company had not accrued any milestone payments to Carna. Milestone payments will be accrued once they are considered probable of occurring.

Lease Agreements

In February 2015, the Company entered into an operating lease agreement to sublease office space in Vancouver, Canada. The operating lease agreement expires on February 27, 2018. Under the terms of the agreement, the Company issued a letter of credit to the sublessor on closing, which was collateralized by a restricted deposit of $25,000 at September 30, 2016.

In January 2016, the Company entered into an operating lease agreement to lease office space near San Francisco, California. The operating lease agreement expires on April 30, 2019.

In addition to base rent, these leases require payment of taxes and other operating costs. These operating costs are not included in the table below.

As of September 30, 2016, the aggregate future non-cancelable minimum lease payments associated with these operating leases are as follows:

Years Ending December 31:	Operating Leases (in thousands)
2016	$ 87
2017	354
2018	209
2019	50
Total	$ 700

The total rent expense for all operating leases was $0.1 million and $0.4 million for the three and nine months ended September 30, 2016 and was $0.1 million and $0.2 million for the three and nine months ended September 30, 2015.

Legal

On November 9, 2016, a purported securities class action lawsuit was filed in the United States District Court for the Southern District of New York against the Company and certain of its executive officers. The lawsuit was brought by purported stockholders of the Company seeking to represent a class consisting of stockholders who purchased stock between July 15, 2015 and June 6, 2016. The lawsuit asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and seeks unspecified damages and other relief. The Company believes that the claims are without merit and intends to defend the lawsuit vigorously. Due to the early stage of the litigation, the Company is unable to predict the outcome of this matter and is unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

From time to time, the Company may become subject to other legal proceedings, claims and litigation arising in the ordinary course of business. In addition, the Company may receive letters alleging infringement of patent or other intellectual property rights. The Company is not currently a party to any other material legal proceedings, nor is it aware of any pending or threatened litigation that, in the Company's opinion, would have a material adverse effect on the business, operating results, cash flows or financial condition should such litigation be resolved unfavorably.

7. Common Stock Reserved for Issuance

The Company is required to reserve and keep available out of its authorized but unissued shares of common stock a number of shares sufficient to effect the conversion of all outstanding options granted and available for grant under the incentive plans and shares reserved for issuance under the employee stock purchase plan.

	September 30, 2016	December 31, 2015
Outstanding and issued stock options	6,629,163	3,522,813
Shares reserved for future option grants	1,327,398	3,523,879
Shares reserved under the 2015 employee stock purchase plan	700,000	700,000
Total common stock reserved for issuance	8,656,561	7,746,692

8. Preferred Stock

Preferred Stock

As of September 30, 2016, the Company had 10,000,000 shares of preferred stock authorized with a par value of $0.001. No shares of preferred stock were outstanding as of September 30, 2016.

Convertible and Redeemable Convertible Preferred Stock

During the year ended December 31, 2015, the Company issued an aggregate of 481,671 shares of redeemable convertible preferred stock upon the cash exercise of the Company's Series B-1 and Series C redeemable convertible preferred stock warrants, consisting of 444,286 shares of Series B-1 redeemable convertible preferred stock and 37,385 shares of Series C redeemable convertible preferred stock.

In addition, during the year ended December 31, 2015, the Company issued an aggregate of 390,032 shares of redeemable convertible preferred stock upon the net exercise of the Company's Series B, Series B-1 and Series C redeemable convertible preferred stock warrants, consisting of 5,850 shares of Series B redeemable convertible preferred stock, 291,165 shares of Series B-1 redeemable convertible preferred stock and 93,017 shares of Series C redeemable convertible preferred stock.

On July 21, 2015 (closing date of the IPO), all outstanding shares of Series A convertible preferred stock converted into 252,817 shares of common stock and all outstanding shares of Series B, Series B-1, Series C and Series D redeemable convertible preferred stock converted into 18,109,136 shares of common stock. On issuance, the Company's convertible and redeemable convertible preferred stock was recorded at fair value or the amount of allocated proceeds, net of issuance costs.

The Company's Series B, B-1, C and D redeemable convertible preferred stock was classified outside of stockholders' equity (deficit) from issuance through the closing of the IPO, because the stock contained redemption features that commenced at any time on or after December 31, 2018 at the election of the Series B, B-1, C and D redeemable convertible preferred stockholders. The Company adjusted the carrying amount of the redeemable convertible preferred stock to equal the redemption value at the end of each reporting period. Due to the absence of retained earnings, adjustments to redemption value were recorded against additional paid-in capital, if any, and then to accumulated deficit. The change in the redemption value of the redeemable convertible preferred stock for the nine months ended September 30, 2015 was as follows:

Redeemable Convertible Preferred Stock	(in thousands)
Series B	$ 46,976
Series B-1	36,961
Series C	52,832
Series D	237,246
Total adjustment to redemption value on redeemable convertible preferred stock	$ 374,015

As the redemption value for the redeemable convertible preferred stock was at times based on fair market value, the Company determined the fair value of the redeemable convertible preferred stock using a combination of the OPM and/or the PWERM models, or the fair value of the Company's common stock. At July 21, 2015 (closing date of the IPO), the fair value of redeemable convertible preferred stock was estimated based on the underlying value of the Company's common stock.

Amendment to Dividend Rights

On June 11, 2015, the Company's stockholders approved an amendment to the Company's Certificate of Incorporation to modify the terms of the cumulative accruing dividends on the outstanding shares of the Company's Series C and Series D redeemable convertible preferred stock. Under the terms of the Amended Certificate of Incorporation, upon conversion of the Company's redeemable convertible preferred stock into common stock in connection with an IPO, the Company was required to pay 50% of the then accrued but unpaid accruing dividends on shares of the Series C and Series D redeemable convertible preferred stock in shares of the Company's common stock instead of payment in cash and the remaining 50% of the then accrued but unpaid accruing dividends was to be forfeited. The settlement of the accrued but unpaid accruing dividends in shares of common stock was required to be at the original issue price of the Series C and Series D redeemable convertible preferred stock of $5.215 per share. The terms of the dividends payable on the Series B and Series B-1 preferred stock were not modified.

Settlement of Cumulative Dividends

On July 21, 2015 (closing date of the IPO), the Company had total cumulative unpaid dividends in arrears of $18.9 million, which consisted of $9.4 million for the Series B, $1.7 million for the Series B-1, $1.7 million for the Series C and $6.1 million for the Series D redeemable convertible preferred stock. During the year ended December 31, 2015, the Company paid in cash accruing dividends in the aggregate amount of $5.5 million to the Series B and B-1 redeemable convertible preferred stockholders, consisting of $4.7 million for the Series B and $0.8 million for the Series B-1 redeemable convertible preferred stockholders. In addition, during the year ended December 31, 2015, the Company issued an aggregate of 750,946 shares of common stock to the Series C and D redeemable convertible preferred stockholders with an aggregate fair value of $20.4 million in settlement of the Series C and Series D redeemable convertible preferred stock cumulative dividends in accordance with the June 11, 2015 amendment discussed above, consisting of 161,536 shares of common stock with a fair value of $4.4 million to the Series C redeemable convertible preferred stockholders and 589,410 shares of common stock with a fair value of $16.0 million to the Series D redeemable convertible preferred stockholders.

9. Preferred Stock Warrants

The Company classified its preferred stock warrants as liabilities. During the year ended December 31, 2015, $19.3 million of the fair value of the warrant liability was reclassified to redeemable convertible preferred stock and then into additional paid-in capital in stockholders' equity (deficit) on conversion of redeemable convertible preferred stock into common stock on the closing of the IPO. The warrants were no longer outstanding at September 30, 2015.

During the year ended December 31, 2015, 31,778 of the Series B-1 warrants were cash exercised at an exercise price of $7.45 per share, 412,508 of the Series B-1 warrants were cash exercised at an exercise price of $2.6075 per share and 37,385 of the Series C warrants were cash exercised at an exercise price of $5.215 per share, resulting in total aggregate cash proceeds to the Company of $1.5 million.

On the closing of the Company's IPO, all of the remaining outstanding preferred stock warrants were net exercised at the IPO price of $17.00 per share, which resulted in 6,499 shares of common stock being issued upon the net exercise of outstanding warrants to purchase 10,414 shares of Series B preferred stock, 291,164 shares of common stock being issued upon the net exercise of outstanding warrants to purchase 349,054 shares of Series B-1 preferred stock and 93,017 shares of common stock being issued upon the net exercise of outstanding warrants to purchase 134,180 shares of Series C preferred stock.

During the nine months ended September 30, 2015, the Company remeasured the preferred stock warrants using the OPM and/or PWERM models, or based on the fair value of the underlying stock. On the closing of the IPO in July 2015, the outstanding preferred stock warrants were exercised and the liability on the preferred stock warrants was reclassified to additional paid-in capital in stockholders' equity (deficit), and was no longer subject to remeasurement.

The change in fair value of the preferred stock warrant liabilities is attributable to the increase of the fair value of the underlying stock. The change in the fair value of preferred stock warrants for the three and nine months ended September 30, 2015 is recognized as a component of other income (expense), net in the condensed consolidated statements of operations.

10. Stock-Based Compensation

In the accompanying condensed consolidated statements of operations, the Company recognized stock-based compensation expense for its employees and non-employees as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
	(in thousands)			
Research and development	$ 863	$ 733	$2,624	$1,032
General and administrative	436	579	1,341	880
Total stock-based compensation	$1,299	$1,312	$3,965	$1,912

Determination of Fair Value

The estimated grant-date fair values of all of the Company's stock-based awards were calculated using the Black-Scholes option pricing model, based on assumptions as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Expected term (in years)	5.1–9.9	6.1	5.1–9.9	5.2–10.0
Expected volatility	80–86%	79%	77–86%	75–84%
Risk-free interest rate	1.1–1.5%	1.7–1.9%	1.1–1.9%	1.5–2.4%
Expected dividend rate	— %	— %	— %	— %

Equity Incentive Plans

2015 Plan

The 2015 Equity Incentive Plan (2015 Plan) became effective on July 14, 2015. Under the 2015 Plan, 3,400,000 shares of common stock were initially reserved for issuance pursuant to a variety of stock-based compensation awards, including stock options, restricted stock awards, stock appreciation rights, restricted stock units, performance awards, cash awards and stock bonuses. In addition, 365,535 shares that had been available for future awards under the 2008 Plan as of July 14, 2015, were added to the initial reserve available under the 2015 Plan, bringing the total number of shares reserved for issuance under the 2015 Plan upon its effective date to 3,765,535 shares. The number of shares initially reserved for issuance under the 2015 Plan will increase automatically on January 1 of each calendar year 2016 through 2025 by the number of shares equal to 4% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31. Accordingly, 1,202,324 shares were added to the reserve available under the 2015 Plan on January 1, 2016. The Company's Board of Directors or Compensation Committee may reduce the amount of the increase in any particular year. The exercise price of each stock-based award issued under the 2015 Plan is required to be no less than the fair value of the Company's capital stock. The vesting and exercise provisions of options or restricted awards granted are determined individually with each grant. Stock options have a 10-year life and expire if not exercised within that period or if not exercised within three months of cessation of employment with the Company or such longer period of time as specified in the option agreement.

2008 Plan

The Company granted options under the 2008 Stock Plan (2008 Plan) until July 2015 when it was terminated as to future awards, although it continues to govern the terms of options that remain outstanding under the 2008 Plan. The 2008 Plan provided for the granting of Incentive Stock Options (ISO), nonqualified stock options and stock purchase rights. In connection with the Board of Director's approval of the 2015 Plan, all remaining shares available for future award under the 2008 Plan were transferred to the 2015 Plan, and the 2008 Plan was terminated.

A summary of activity under the 2008 Plan and 2015 Plan and related information is as follows:

	Shares Available for Grant	Options Outstanding			
		Number of Shares Outstanding	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value of Outstanding Options (in thousands)
Outstanding — December 31, 2015	3,523,879	3,522,813	$ 3.81	8.78	$ 40,425
Awards authorized	1,202,324				
Options granted	(3,702,880)	3,702,880	3.22		
Options exercised	—	(292,455)	0.66		
Options forfeited/cancelled	304,075	(304,075)	7.89		
Outstanding — September 30, 2016	1,327,398	6,629,163	$ 3.43	9.09	$ 1,443
Exercisable — September 30, 2016		2,244,374	$ 2.01	8.04	$ 1,443
Vested and expected to vest — September 30, 2016		6,394,550	$ 3.42	9.08	$ 1,418

The weighted-average grant date fair values of options granted during the three and nine months ended September 30, 2016 was $1.26 and $2.20 per share and during the three and nine months ended September 30, 2015 was $23.60 and $10.19 per share. The aggregate intrinsic value of options exercised was $0.2 million and $1.2 million for the three and nine months ended September 30, 2016 and $0.2 million for the three and nine months ended September 30, 2015. The total grant date fair value of options vested for the three and nine months ended September 30, 2016 was $0.9 million and $4.4 million and during the three and nine months ended September 30, 2015 was $0.7 million and $0.9 million.

As of September 30, 2016, total unrecognized stock-based compensation related to unvested stock options was $15.4 million, net of estimated forfeitures. These costs are expected to be recognized over a remaining weighted-average period of 2.8 years as of September 30, 2016.

Liability for Early Exercise of Stock Options

The 2008 Plan allows for the granting of options that may be exercised before the options have vested. In December 2014, an executive officer early exercised 103,252 stock options. In February 2015, an executive officer early exercised 13,422 stock options. On early exercise, the awards became subject to a restricted stock agreement. The shares of restricted stock granted upon early exercise of the options are subject to the same vesting provisions as the original stock option awards. Shares issued as a result of early exercise that have not vested are subject to repurchase by the Company upon termination of the purchaser's employment or services, at the price paid by the purchaser, and are not deemed to be issued for accounting purposes until those related shares vest. The liability is reclassified into common stock and additional paid-in capital as the shares vest and the repurchase right lapses. As at September 30, 2016, all stock granted upon early exercise of the options have vested and as such, the Company has no outstanding liability related to the early exercise of stock options. As of December 31, 2015, the Company recorded the unvested portion of the exercise proceeds of $23,000 as a current liability in the accompanying condensed consolidated balance sheets. As of December 31, 2015, 23,554 shares held by the employees were unvested and subject to repurchase.

2015 Employee Stock Purchase Plan

The Company adopted the 2015 Employee Stock Purchase Plan (ESPP) and initially reserved 700,000 shares of common stock as of its effective date of July 15, 2015. The number of shares initially reserved for issuance under the ESPP will increase automatically on January 1 for nine years from the first offering date by the number of shares equal to 1% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31. The aggregate number of shares issued over the term of the 2015 Employee Stock Purchase Plan will not exceed 3,400,000 shares of common stock.

Under the ESPP, participants are offered the options to purchase shares of the Company's common stock at a 15% discount during a series of discrete offering periods, subject to any plan limitations. The ESPP will not become effective until such time as the Compensation Committee determines in the future, and as of September 30, 2016, the initial offering periods had not commenced. As of September 30, 2016, no shares of common stock have been issued to employees participating in the ESPP and 700,000 shares were available for issuance under the ESPP.

11. Income Taxes

The Company did not record a provision for U.S. federal income taxes for the three and nine months ended September 30, 2016 because it expects to generate a loss for the year ended December 31, 2016. The income tax expense of $14,000 and $36,000 for the three and nine months ended September 30, 2016 represents foreign taxes. The Company's net U.S. deferred tax assets continue to be offset by a full valuation allowance.

12. Restructuring Costs

In June 2016, the Company halted investment in PNT2258 and the DNAi platform and closed the related Phase 2 clinical trials to further enrollment. As a result, the Company closed its research facility in Plymouth, Michigan, renegotiated and terminated certain contracts, and implemented staff reductions in the United States and Canada.

The following table summarizes restructuring activities for the three months ended September 30, 2016:

	Contract Termination	Employee Termination	Asset Impairment	Total
		(in thousands)		
Accrual balance at June 30, 2016	$ 2,093	$ 57	$ —	$2,150
Adjustments to research and development expense	(420)	—	—	(420)
Restructuring costs charged to general and administrative expense	—	100	—	100
Cash payments	(254)	(101)	—	(355)
Accrual balance at September 30, 2016	$ 1,419	$ 56	$ —	$1,475

Adjustments to research and development expense include revisions to estimated costs to close the PNT2258 Phase 2 clinical trials.

The following table summarizes restructuring activities for the nine months ended September 30, 2016:

	Contract Termination	Employee Termination	Asset Impairment	Total
		(in thousands)		
Accrual balance at December 31, 2015	$ —	$ —	$ —	$ —
Restructuring costs charged to research and development expense	2,367	—	—	2,367
Restructuring costs charged to general and administrative expense	5	286	130	421
Non-cash charges	(681)	—	(130)	(811)
Cash payments	(272)	(230)	—	(502)
Accrual balance at September 30, 2016	$ 1,419	$ 56	$ —	$1,475

The accrual balance is expected to be fully paid in early 2017.

There were no restructuring activities during the three and nine months ended September 30, 2015.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with the unaudited consolidated financial statements and the notes thereto included in Part I, Item 1 of this report and with our audited consolidated financial statements and related notes thereto for the year ended December 31, 2015, included in our Annual Report on Form 10-K. This discussion and other parts of this report contain forward-looking statements that involve risks and uncertainties, such as our plans, objectives, expectations, intentions and beliefs. Our actual results could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in the section entitled "Risk Factors" included elsewhere in this report.

Overview

We are a clinical-stage drug development company focused on advancing targeted therapeutics for the treatment of patients with cancer. We are an ambitious oncology focused company oriented towards achieving the successful registration and commercialization of our product candidates. We have a world-class management team with a proven track record of success in oncology drug development and we are building a broad and diverse pipeline of promising oncology assets against emerging targets on the leading edge of cancer biology.

Our lead drug candidate, PNT737, is a highly selective, orally bioavailable small molecule inhibitor of Checkpoint kinase 1 (Chk1), a central regulator of the DNA Damage Response (DDR) network. In cancer cells, replication stress induced by oncogenes (e.g. MYC and RAS oncogenes) combined with loss of function in tumor suppressors (e.g. p53 and ATM tumor suppressor genes) results in persistent DNA damage and genomic instability. Targeted inhibition of the remaining components of the DDR network such as by PNT737 may be synthetically lethal to cancer cells and have utility as a monotherapy in a range of tumor indications. Chk1 is also believed to facilitate tumor cell resistance to chemotherapy or radiation-induced DNA damage and the combination of PNT737 with these standards-of-care may provide synergistic anti-tumor activity. PNT737 is currently being investigated in two Phase 1 clinical trials in patients with advanced cancer at the Royal Marsden NHS Foundation Trust and other centers in the UK. We anticipate expanding on the current clinical program underway for PNT737, including into the United States, with the expectation of filing an Investigational New Drug application (IND) in the second half of 2017.

We are also advancing PNT141, a highly selective, orally bioavailable small molecule inhibitor of cell division cycle 7 kinase (Cdc7). Cdc7 is a key regulator of both DNA replication and the DDR network, making it a compelling emerging target for the potential treatment of a broad range of tumor types. As both Chk1 and Cdc7 have potentially complementary cell cycle checkpoint and DDR functions, inhibiting both of these targets simultaneously may be advantageous. This potential biological synergy presents opportunities for novel proprietary combination strategies involving PNT737 and PNT141. PNT141 is currently undergoing preclinical development with an IND filing anticipated in the second half of 2017.

We continue to seek and evaluate additional assets for potential in-licensing or acquisition, with the objective of expanding the number of products we have in our portfolio and in order to leverage the full potential of our team.

In June 2016, we suspended the development of PNT2258, our former lead product candidate, based on our review of the interim results from a Phase 2 trial of PNT2258. Although we observed modest efficacy from PNT2258 in this interim analysis, we did not view these data as robust enough to justify continued development of the drug. No further investment in PNT2258 or the underlying DNAi platform is contemplated and we subsequently have closed our research facility based in Plymouth, Michigan, which supported these programs.

Since inception, we have devoted substantially all of our resources to research and development activities, including the clinical development of PNT2258, and providing general and administrative support for these operations. We have never generated revenue and have incurred significant net losses since inception. Our net losses were $15.2 million and $38.6 million for the three and nine months ended September 30, 2016 and were $18.5 million and $41.8 million for the three and nine months ended September 30, 2015. As of September 30, 2016, we had an accumulated deficit of $572.8 million. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- invest to further develop our product candidates, PNT737, a small molecule inhibitor targeting Chk1 and PNT141, a small molecule inhibitor targeting Cdc7;
- acquire or in-license additional product candidates and technologies;
- develop additional product candidates;

- hire additional clinical, scientific and management personnel;
- invest in scaling our manufacturing capacity to support development and our global commercialization strategy;
- seek regulatory and marketing approvals for any product candidates that we may develop;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drugs for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts and to operate as a public company.

On July 21, 2015, we completed the initial public offering (IPO) of our common stock pursuant to a registration statement on Form S-1. In the IPO, we sold an aggregate of 9,315,000 shares of our common stock, which included 1,215,000 shares of common stock purchased by the underwriters upon the full exercise of their options to purchase additional common stock, at a price of $17.00 per share. We received aggregate cash proceeds of approximately $143.6 million from the IPO, net of underwriting discounts and commissions and offering expenses.

We have funded our operations to date primarily from the issuance and sale of our common stock in our IPO and our convertible and redeemable convertible preferred stock in private financings and, to a lesser extent, through debt financings and exercises of our preferred stock warrants. As of September 30, 2016, we had cash and cash equivalents of $122.7 million. Subsequent to the end of the quarter, we paid the $7.0 million upfront payment due to CRT Pioneer Fund LP (CPF) for the exclusive license of PNT737.

Components of Statements of Operations

Operating Expenses

Research and Development

Research and development expenses consist primarily of the following:

- fees or milestone payments incurred in connection with license agreements;
- personnel-related costs, which include salaries, benefits, stock-based compensation, recruitment fees and travel costs;
- costs associated with preclinical studies and clinical trials, regulatory activities and manufacturing activities to support clinical activities;
- fees paid to external service providers that conduct certain research and development, clinical and manufacturing activities on our behalf; and
- facility-related costs, which include direct and allocated expenses for rent and maintenance of facilities, depreciation and amortization expenses and other supplies.

The largest recurring component of our total operating expenses has historically been our investment in research and development activities, including the clinical development of PNT2258. We expect our research and development expenses will increase over the next few years as we advance our development programs, pursue regulatory approval of our product candidates in the United States and other jurisdictions, expand our portfolio of product candidates and prepare for potential commercialization, which will require a significant investment in areas related to contract manufacturing and inventory buildup.

The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing approval for PNT737, PNT141 or any future product candidates. The probability of success of our product candidates may be affected by numerous factors, including clinical data, regulatory developments, competition, manufacturing capability and commercial viability. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization of PNT737, PNT141 or any future product candidates.

General and Administrative

General and administrative expenses consist of personnel-related costs, facility-related costs, allocated expenses and professional fees for services, including legal, human resources, audit and accounting services. Personnel-related costs consist of salaries, benefits, stock-based compensation, recruitment fees, severance costs and travel costs.

We expect to incur additional expenses associated with supporting our growing research and development activities, operating as a public company and other administration and professional services.

Restructuring Costs included in Research and Development and General and Administrative

In June 2016, we halted investment in PNT2258 and the DNAi platform and closed the related Phase 2 clinical trials to further enrollment. As a result, we closed our research facility in Plymouth, Michigan, renegotiated and terminated certain contracts, and implemented staff reductions in the United States and Canada.

The following table summarizes restructuring activities for the three months ended September 30, 2016:

	Contract Termination	Employee Termination	Asset Impairment	Total
	(in thousands)			
Accrual balance at June 30, 2016	$ 2,093	$ 57	$ —	$2,150
Adjustments to research and development expense	(420)	—	—	(420)
Restructuring costs charged to general and administrative expense	—	100	—	100
Cash payments	(254)	(101)	—	(355)
Accrual balance at September 30, 2016	$ 1,419	$ 56	$ —	$1,475

Adjustments to research and development expense include revisions to estimated costs to close the PNT2258 Phase 2 clinical trials.

The following table summarizes restructuring activities for the nine months ended September 30, 2016:

	Contract Termination	Employee Termination	Asset Impairment	Total
	(in thousands)			
Accrual balance at December 31, 2015	$ —	$ —	$ —	$ —
Restructuring costs charged to research and development expense	2,367	—	—	2,367
Restructuring costs charged to general and administrative expense	5	286	130	421
Non-cash charges	(681)	—	(130)	(811)
Cash payments	(272)	(230)	—	(502)
Accrual balance at September 30, 2016	$ 1,419	$ 56	$ —	$1,475

Other Income (Expense), Net

Change in Fair Value of Preferred Stock Warrants

Our preferred stock warrants were previously classified as a liability on our condensed consolidated balance sheets and, as such, were re-measured to fair value at each balance sheet date, with the corresponding gain or loss from the adjustment recorded in the condensed consolidated statement of operations. Upon the completion of the IPO, the liability on the outstanding preferred stock warrants was reclassified to additional paid-in capital in stockholders' equity (deficit).

Other Income

Other income primarily consists of interest earned on our cash and cash equivalents and short-term investments, as well as foreign currency exchange gains and losses. Foreign currency exchange gains and losses relate to transactions and monetary asset and liability balances denominated in currencies other than the U.S. dollar. Foreign currency gains and losses may continue to fluctuate in the future due to changes in foreign currency exchange rates.

Provision for Income Taxes

Provision for income taxes consists of federal and state income taxes in the United States and income taxes in Canada and Australia, as well as deferred income taxes and changes in related valuation allowance, reflecting the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes.

We did not record a provision for U.S. federal income taxes for the three and nine months ended September 30, 2016 because we expect to generate a loss for the year ended December 31, 2016. Our tax expense to date relates to income taxes in Canada and Australia. Our net U.S. deferred tax assets continue to be offset by a full valuation allowance.

Results of Operations

Three Months Ended September 30, 2016 Compared to Three Months Ended September 30, 2015

	Three Months Ended September 30,		Change
	2016	2015	$
	(in thousands)		
Operating expenses:			
Research and development	$ 12,323	$ 8,295	$ 4,028
General and administrative	2,960	2,738	222
Total operating expenses	15,283	11,033	4,250
Loss from operations	(15,283)	(11,033)	(4,250)
Other income (expense), net:			
Change in fair value of preferred stock warrants	—	(7,487)	7,487
Other income	88	29	59
Total other income (expense), net	88	(7,458)	7,546
Loss before provision for income taxes	(15,195)	(18,491)	3,296
Provision for income taxes	14	14	—
Net loss	$(15,209)	$(18,505)	$ 3,296

Research and Development

Research and development expenses increased $4.0 million, from $8.3 million for the three months ended September 30, 2015, to $12.3 million for the three months ended September 30, 2016. The increase was primarily due to a $7.0 million upfront fee due to CPF for the exclusive license of PNT737 to us, and a $2.0 million fee that will be due upon the successful transfer of two ongoing clinical trials in accordance with the license agreement. The remaining increase was attributable to a $0.6 million increase in personnel-related costs due mainly to increased headcount, of which $0.1 million was attributable to stock-based compensation. These increased costs were partially offset by a $3.0 million decrease in third-party manufacturing costs, a $2.2 million decrease in research, preclinical and clinical costs and a $0.4 million restructuring charge adjustment.

General and Administrative

General and administrative expenses increased $0.2 million, from $2.7 million for the three months ended September 30, 2015 to $3.0 million for the three months ended September 30, 2016. The increase was attributable to a $0.3 million increase relating to business development activities and a $0.1 million restructuring charge related to employee termination. These increased costs were offset by a $0.2 million decrease in professional services costs.

Change in Fair Value of Preferred Stock Warrants

The change in the fair value of our preferred stock warrants decreased $7.5 million, from $7.5 million for the three months ended September 30, 2015 to nil for the three months ended September 30, 2016. The preferred stock warrants were exercised immediately prior to the closing of the IPO, which closed on July 21, 2015.

Nine Months Ended September 30, 2016 Compared to Nine Months Ended September 30, 2015

	Nine Months Ended September 30,		Change
	2016	2015	$
	(in thousands)		
Operating expenses:			
Research and development	$ 28,074	$ 18,329	$ 9,745
General and administrative	10,768	6,053	4,715
Total operating expenses	38,842	24,382	14,460
Loss from operations	(38,842)	(24,382)	(14,460)
Other income (expense), net:			
Change in fair value of preferred stock warrants	—	(17,443)	17,443
Other income	259	48	211
Total other income (expense), net	259	(17,395)	17,654
Loss before provision for income taxes	(38,583)	(41,777)	3,194
Provision for income taxes	36	25	11
Net loss	$(38,619)	$(41,802)	$ 3,183

Research and Development

Research and development expenses increased $9.7 million, from $18.3 million for the nine months ended September 30, 2015, to $28.1 million for the nine months ended September 30, 2016. The increase was primarily due to a $7.0 million upfront fee due to CPF, a $2.0 million fee that will be due upon the successful transfer of two ongoing clinical trials in accordance with the license agreement and a $0.9 million upfront fee paid to Carna Biosciences, Inc. for the exclusive license of PNT141. The remaining increase was attributable to a $2.4 million restructuring charge related to the halt in investment in PNT2258 and the DNAi platform and a $4.3 million increase in personnel-related costs due mainly to increased headcount, of which $1.6 million was attributable to stock-based compensation. These increased costs were partially offset by a $6.0 million decrease in third-party manufacturing costs and a $0.9 million decrease in research, preclinical and clinical costs.

General and Administrative

General and administrative expenses increased $4.7 million, from $6.1 million for the nine months ended September 30, 2015 to $10.8 million for the nine months ended September 30, 2016. The increase was primarily due to a $2.1 million increase in personnel-related costs associated mainly with increased headcount, of which $0.5 million was attributable to an increase in stock-based compensation. The remaining increase was attributable to a $1.1 million increase relating to business development activities, a $0.9 million increase in allocated overhead expenses primarily related to increased headcount in support of corporate growth, a $0.4 million restructuring charge related to employee termination and asset impairment and a $0.2 million increase in professional fees incurred in connection with activities related to being a public company.

Change in Fair Value of Preferred Stock Warrants

The change in the fair value of our preferred stock warrants decreased $17.4 million, from $17.4 million for the nine months ended September 30, 2015 to nil for the nine months ended September 30, 2016. The preferred stock warrants were exercised immediately prior to the closing of the IPO, which closed on July 21, 2015.

Liquidity and Capital Resources

Capital Resources

Since our inception, we have never generated revenue and have incurred significant net losses. Our net losses for the three and nine months ended September 30, 2016 were $15.2 million and $38.6 million and for the three and nine months ended September 30, 2015 were $18.5 million and $41.8 million. As of September 30, 2016, we had an accumulated deficit of $572.8 million. Our principal sources of liquidity as of September 30, 2016 were cash and cash equivalents of $122.7 million. Subsequent to the end of the quarter, we paid the $7.0 million upfront payment due to CPF for the exclusive license of PNT737.

In July 2015, we closed our IPO and sold an aggregate of 9,315,000 shares of our common stock (inclusive of 1,215,000 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares) at a price of $17.00 per share. We received aggregate cash proceeds of approximately $143.6 million from the IPO, net of underwriting discounts and commissions and offering expenses. As of September 30, 2016, we did not have any outstanding borrowings or any debt arrangements.

We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our expenses will increase substantially as we:

- invest to further develop our product candidates, PNT737, a small molecule inhibitor of Chk1 and PNT141, a small molecule inhibitor targeting Cdc7;
- acquire or in-license additional product candidates and technologies;
- develop additional product candidates;
- hire additional clinical, scientific and management personnel;
- invest in scaling our manufacturing capacity to support development and our global commercialization strategy;
- seek regulatory and marketing approvals for any product candidates that we may develop;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drugs for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management information systems and personnel, including personnel to support our drug development, any future commercialization efforts and to operate as a public company.

To fund our current operating plans, we will need to raise additional capital. Our existing cash and cash equivalents will not be sufficient for us to complete development of our product candidates and, if applicable, to prepare for commercializing any product candidate that may receive approval. Accordingly, we will continue to require substantial additional capital to continue our clinical development and potential commercialization activities; however, we believe that our existing cash and cash equivalents will be sufficient to fund our current operating plans through at least the next 18 months. We cannot assure that we will ever be profitable or generate positive cash flow from operating activities. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts.

We plan to continue to fund our current operating plans' needs through equity financings or other arrangements. To the extent that we raise additional capital through future equity financings, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. If we raise additional funds through the issuance of debt securities, these securities could contain covenants that would restrict our operations. There can be no assurance that such additional financing, if available, can be obtained on terms acceptable to us. If we are unable to obtain such additional financing, we would need to reevaluate our future operating plans.

Cash Flows

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

	Nine Months Ended September 30,	
	2016	2015
	(in thousands)	
Cash used in operating activities	$(27,499)	$ (21,189)
Cash (used in) provided by investing activities	(128)	9,479
Cash provided by financing activities	179	139,876
Effect of foreign exchange rate changes on cash and cash equivalents	(50)	(12)
Net (decrease) increase in cash and cash equivalents	$(27,498)	$128,154

Cash Flows from Operating Activities

For the nine months ended September 30, 2016, cash used in operating activities of $27.5 million was attributable to a net loss of $38.6 million, partially offset by $5.0 million in non-cash charges and a net change of $6.2 million in our net operating assets and liabilities. The non-cash charges consisted primarily of $4.0 million in stock-based compensation and $0.8 million in non-cash restructuring charges. The change in net operating assets and liabilities was primarily attributable to a $9.0 million charge related to the exclusive license of PNT737 to us pursuant to a license agreement with CPF, which was included in accrued research and development costs.

For the nine months ended September 30, 2015, cash used in operating activities of $21.2 million was attributable to a net loss of $41.8 million, partially offset by $19.4 million in non-cash charges and a net change of $1.2 million in our net operating assets and liabilities. The non-cash charges consisted primarily of $17.4 million for the change in fair value of our preferred stock warrants and $1.9 million in stock-based compensation. The change in operating assets and liabilities was primarily attributable to an increase in accrued research and development costs.

Cash Flows from Investing Activities

For the nine months ended September 30, 2016, cash used in investing activities of $0.2 million was primarily attributable to the purchase of property and equipment, partially offset by proceeds received from the sale of property and equipment.

For the nine months ended September 30, 2015, cash provided by investing activities of $9.5 million was attributable to $10.0 million in proceeds from the sale of short-term investments, partially offset by the purchases of property and equipment and cash transferred to a restricted cash account as collateral for our corporate credit cards and facility lease.

Cash Flows from Financing Activities

For the nine months ended September 30, 2016, cash provided by financing activities was $0.2 million, consisting of proceeds received from the exercise of options to purchase common stock.

For the nine months ended September 30, 2015, cash provided by financing activities was $139.9 million, consisting primarily of $143.9 million in net proceeds (including the payment of $3.4 million of deferred offering costs) received from the issuance of common stock upon our IPO and $1.5 million in proceeds received from the cash exercise of redeemable convertible preferred stock warrants. This change was partially offset by the payment of $5.5 million to the holders of the Series B and Series B-1 redeemable convertible preferred stock in settlement of the cumulative dividend provisions on IPO.

Off-Balance Sheet Arrangements

We do not currently engage in off-balance sheet financing arrangements. In addition, we do not have any interest in entities referred to as variable interest entities, which includes special purpose entities and other structure finance entities.

Critical Accounting Policies and Estimates

Our condensed consolidated financial statements are prepared in accordance with U.S. generally accepted accounting principles (GAAP). The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and related disclosures. These estimates form the basis for judgments we make about the carrying values of our assets and liabilities, which are not readily apparent from other sources. We base our estimates and judgments on historical experience and on various other assumptions that we believe are reasonable under the circumstances. On an ongoing basis, we evaluate our estimates and assumptions. Our actual results may differ from these estimates under different assumptions or conditions.

We believe that the assumptions and estimates associated with research and development expenses, stock-based compensation and preferred stock warrant liabilities have the most significant impact on our condensed consolidated financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in Management's Discussion and Analysis of Financial Condition and Operations included in our Annual Report on Form 10-K for the year ended December 31, 2015.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Sensitivity

We had cash and cash equivalents of $122.7 million as of September 30, 2016, which consisted primarily of bank deposits and money market funds. Subsequent to the end of the quarter, we paid the $7.0 million upfront payment due to CPF for the exclusive license of PNT737. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our condensed consolidated financial condition or results of operations. We do not believe that our cash or cash equivalents have significant risk of default or illiquidity.

Foreign Currency Risk

Our condensed consolidated results of operations and cash flows are subject to fluctuations due to changes in foreign currency exchange rates. A substantial majority of our expenses are denominated in U.S. Dollars, with the remainder in Canadian and Australian Dollars. Our condensed consolidated results of operations and cash flow are, therefore, subject to fluctuations due to changes in foreign currency exchange rates and may be adversely affected in the future due to changes in foreign exchange rates. To date, we have not entered into any hedging arrangements with respect to foreign currency risk or other derivative instruments. The effect of a hypothetical 10% change in foreign currency exchanges rates applicable to our business would not have a material impact on our operating loss.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated 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) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of September 30, 2016 to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely discussion regarding required disclosures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II

ITEM 1. LEGAL PROCEEDINGS

On November 9, 2016, a purported securities class action lawsuit was filed in the United States District Court for the Southern District of New York against us and certain of our executive officers. The lawsuit was brought by purported stockholders of our company seeking to represent a class consisting of stockholders who purchased stock between July 15, 2015 and June 6, 2016. The lawsuit asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and seeks unspecified damages and other relief. We believe that the claims are without merit and intend to defend the lawsuit vigorously. Due to the early stage of the litigation, we are unable to predict the outcome of this matter and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from an unfavorable outcome.

From time to time, we may become involved in various other claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any other legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this report, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment.

Risks Related to Our Business and Industry

We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses for the foreseeable future.

We are a clinical-stage oncology company with a limited operating history. Since inception, we have incurred significant operating losses. Our net losses were $38.6 million and $53.3 million for the nine months ended September 30, 2016 and the year ended December 31, 2015, respectively. As of September 30, 2016, we had an accumulated deficit of $572.8 million. Investment in oncology product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. For example, in June 2016 we decided to suspend the development of PNT2258 after an interim analysis of data from a Phase 2 clinical trial of PNT2258 indicated only modest efficacy. We have no products approved for commercial sale and have not generated any revenue to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue the development of our product candidates, PNT737 and PNT141, fund preclinical and clinical studies, seek to identify additional product candidates, seek regulatory approval, prepare for potential commercialization and operate as a public company.

Even if we succeed in commercializing PNT737, PNT141 or any future product candidates we may develop, we will continue to incur substantial research and development and other expenditures to develop and market these and other product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity (deficit) and working capital.

Our business is highly dependent on the success of our product candidates, PNT737 and PNT141. If we are unable to successfully develop, obtain regulatory approval for and commercialize PNT737 and PNT141, or experience significant delays in doing so, our business will be materially harmed.

Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize our product candidates, PNT737 and PNT141, which are both at early stages of development. We have invested effort and financial resources in the research and development of PNT737 and PNT141, and both PNT737 and PNT141 will require significant additional preclinical and clinical testing before we can seek regulatory approval and potentially launch commercial sales. Further development of PNT737 and PNT141 will require additional preclinical and clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales, if approved.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval for the product candidates from the U.S. Food and Drug Administration (FDA). Similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from similar regulatory authorities outside of the United States, such as the European Medicines Agency in Europe and the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom. Even if PNT737, PNT141 or another product candidate were to be approved by the FDA or foreign regulatory authorities, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or

contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval for PNT737 or PNT141 in one or more jurisdictions, or any approval contained significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development, marketing or commercialization of PNT737, PNT141 or any other product candidate that we may acquire or develop in the future. Furthermore, even if we obtain regulatory approval for either of our product candidates, we will still need to develop a commercial organization, or collaborate with a third party for the commercialization of our product candidates, establish commercially viable pricing and obtain approval for coverage and adequate reimbursement from third parties, including government payors. If we are unable to successfully commercialize either of our product candidates, we may not be able to generate sufficient revenues to continue our business.

We are early in our development efforts, and our lead product candidate has only been tested in a limited number of patients. If we are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are safe and effective for use in their target indications before we can seek regulatory approval for their commercial sale. There have been two Clinical Trial Authorisations, or CTAs, granted by the MHRA in the United Kingdom for PNT737 and two Phase 1 trials have been initiated in the United Kingdom. We plan to continue our PNT737 development efforts by conducting further preclinical studies to further our understanding of PNT737, support an Investigational New Drug (IND) application in the US and support future clinical development. PNT141 has never been evaluated in human clinical trials. We will need to conduct additional preclinical studies of PNT141 that demonstrate it has an acceptable safety profile for the treatment of patients and that support an IND application and further development of the product candidate.

The success of our product candidates and any future product candidates that we may acquire or develop will depend on several factors, including the following:

- completion of preclinical efficacy and toxicology studies with positive results;
- successful enrollment in, and completion of, clinical trials with positive results;
- receipt of marketing approvals from applicable regulatory authorities;
- establishment of commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- effective patent and trade secret protection and regulatory exclusivity;
- establishment of a commercial sales team, if and when approved, whether alone or in collaboration with others;
- acceptance, if and when approved, by patients, the medical community and third-party payors;
- coverage and adequate reimbursement by third-party payors, including government payors;
- our ability to compete with other therapies;
- continued acceptable safety profile following approval;
- enforcement of intellectual property rights and claims;
- achievement of desirable medicinal properties for the intended indications; and
- effective growth of an organization of scientists and business people who can develop and commercialize the products, if approved, and technology.

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

If we are unable to timely or fully transition the development activities for PNT737 from Cancer Research UK to us, our business and ability to continue development of PNT737 would be harmed.

As a component of our licensing agreement with CRT Pioneer Fund LP (CPF), we have entered into a transition plan with Cancer Research UK (CRUK) under which we will coordinate the transition of clinical and related development and manufacturing responsibilities from CRUK. The transition of these activities, including the time necessary to transfer regulatory sponsorship of the ongoing Phase 1 clinical trials of PNT737, transfer clinical site agreements for the ongoing trials, and identify, test and establish manufacturing capabilities with a third party manufacturer, among other things, could cause delays in the clinical progress and development of PNT737. Additionally, until the transfer process is complete, CRUK remains the sponsor of the ongoing trials, and as such, has final decision making authority over the conduct of the trials and may make decisions that we would otherwise not make or support.

Further, CRUK has historically been responsible for all development activities, including drug process, preclinical development activities, submission of the CTAs, development of the protocol and establishment of clinical and safety databases. Although we believe the historical development activities have been conducted in accordance with all applicable rules and regulations, we cannot assure you that we will not discover inaccuracies or noncompliance in prior development activities that have an adverse effect on the future development of PNT737.

If further preclinical development or clinical trials of PNT737, PNT141 or future product candidates that we may develop or acquire fail to demonstrate safety and efficacy or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of PNT737, PNT141 or future product candidates.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later preclinical testing and clinical trials, and interim results of a clinical trial do not necessarily predict final results. Many companies in the biotechnology industry have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and there is a high failure rate for product candidates proceeding through clinical trials. For example, in June 2016, we announced that we decided to suspend the development of PNT2258 after an interim analysis of data from a Phase 2 clinical trial of PNT2258 indicated only modest efficacy. We cannot, therefore, guarantee that we will be successful in obtaining the required efficacy and safety profile from either PNT737 or PNT141. A failure of one or more preclinical studies or clinical trials can occur at any stage of testing.

We are currently conducting preclinical assessments of PNT737 and PNT141 that we believe will further inform our clinical development plans and patient selection strategies. We are also planning to complete various other tasks and activities, such as those related to toxicology and manufacturing, with the objective of submitting an IND for PNT737 in the second half of 2017 and advancing PNT141 into clinical trials by the end of 2017. However, we have not yet discussed such preclinical development with the FDA, and we may receive feedback from the FDA that delays our expected development timeline.

Before obtaining marketing approval from regulatory authorities, including the FDA, for the sale of our product candidates, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Because the preclinical studies conducted in the United Kingdom to support PNT737's CTAs will not be accepted by the FDA to support an IND submission, we will be required to conduct additional preclinical studies of PNT737. Preclinical studies of our product candidates may not ultimately support an IND submission or complicate further clinical development.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and even if the trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. To the extent that the results of our studies and trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates.

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

- undesirable side effects or other unexpected characteristics of our product candidates, causing us or our investigators, regulators or institutional review boards (IRBs) to suspend or terminate the trials;
- regulators or IRBs may not authorize us or our investigators to initiate a clinical trial, conduct a clinical trial at a prospective trial site;
- government or regulatory delays and changes in regulatory requirements, policy and guidelines;
- delays in reaching or failure to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and contract research organizations (CROs), or failure by such CROs or trials sites to carry out the clinical trial in accordance with the terms of our agreements with them;
- negative or inconclusive results of preclinical studies or clinical trials;
- decision by us to conduct additional preclinical studies or clinical trials or abandon product development programs;
- a higher number of patients required for clinical trials, slower than expected enrollment, greater than expected competition for patients or higher than expected drop out rates;

- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment;
- failure of third-party contractors to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- inability or unwillingness of patients or medical investigators to follow our clinical trial protocols;
- suspension or termination of clinical trials for various reasons, including unacceptable health risks;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or site by the FDA or foreign regulatory authorities;
- greater than expected cost of clinical trials;
- insufficient supply or quality of product candidates or other materials necessary to conduct clinical trials; and
- revision of legal or regulatory requirements for approving our product candidates.

If we are required to conduct additional preclinical studies or clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete preclinical studies and clinical trials of our product candidates or other testing, if the results of these studies, trials or tests reflect an unacceptable safety profile, or are not positive or are only modestly positive, we may:

- be delayed or unable to submit an IND, or an IND may be rejected by the FDA;
- be delayed in obtaining marketing approval;
- not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any preclinical studies or clinical trials will continue as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical studies and clinical trial delays also could allow our competitors to bring products to market before we do and could impair our ability to successfully commercialize our product candidates, any of which may harm our business and results of operations.

If we fail to obtain additional capital, we may be unable to acquire additional product candidates and complete the development and commercialization of our product candidates.

We expect to spend substantial capital to acquire additional product candidates and advance PNT737 and PNT141 in preclinical and clinical development, seek regulatory approvals for our product candidates, establish a commercial sales force to market and manufacture products, if any, that are approved for commercial sale. We also incur significant additional compliance and administrative costs as a result of operating as a public company.

Our future capital requirements will depend on many factors, including:

- the progress and results of our planned preclinical studies and clinical trials;
- the scope, progress, results and costs of product candidate discovery, preclinical development, laboratory testing and clinical trials for our future product candidates;
- the costs, timing and outcome of regulatory review of PNT737, PNT141 and any future product candidates;
- the costs of future commercialization activities, including drug sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval, to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator;
- the extent to which we acquire or in-license other drugs and technologies;

- our ability to establish and maintain collaborations on favorable terms, if at all;
- the success of any collaborations that we may enter into with third parties;
- the timing and amount of milestone and royalty payments;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our drug candidates receive marketing approval; and
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of our product candidates, if approved, which we do not expect to be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. We also may be unable to acquire additional promising product candidates.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the number of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for patients and clinical trial sites;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population;
- the risk that disease progression will result in death or clinical deterioration before the patient can enroll in clinical trials or before sufficient data has been collected such that the patient contributes no meaningful information for the clinical trial in which the patient is enrolled;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates. This competition will reduce the number and types of patients and qualified clinical investigators available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials are already being conducted there. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. We may also encounter difficulties finding a clinical trial site at which to conduct our trials. Moreover, because our product candidates represent an experimental medicine, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy, radiation and other approved therapies, rather than enroll patients in any one of our clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of our product candidates or any future product candidates we may develop.

The manufacture of PNT737 and PNT141 requires outsourced, custom manufacturing and we may encounter difficulties in production, particularly with respect to formulation, process development or scaling up of our manufacturing capabilities. If our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for preclinical studies, clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

As product candidates are developed, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned preclinical studies or future clinical trials.

Currently, PNT737 and PNT141 are manufactured using unoptimized processes by third-party manufacturers. Although we are working to develop a commercially viable manufacturing process, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale up or formulation, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials.

Any of these challenges could delay completion of preclinical studies or clinical trials, require bridging studies or trials, or the repetition of one or more studies or trials, increase development costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our reliance on third-party manufacturing partners may cause our supply of research and development, preclinical and clinical development materials to become limited or interrupted or fail to be of satisfactory quantity or quality.

We do not have any manufacturing facilities or personnel. We currently rely, and expect to continue to rely, on third parties for the manufacture of PNT737 and PNT141 and any future potential product candidates that we may develop for preclinical and clinical testing, as well as for commercial manufacture if our product candidates receive marketing approval. We have engaged third-party manufacturers to obtain materials and consumables necessary for the manufacture of PNT737 and PNT141.

We may be unable to establish further agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for sufficient quantity and quality;
- the possible breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- misappropriation of our proprietary information, including our trade secrets and know-how;
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and
- reliance on the third party for regulatory compliance, quality assurance and safety reporting.

While we require our third-party manufactures to comply with current good manufacturing practices (cGMPs), these third-party manufacturers may cease to continue to comply with cGMPs or similar regulatory requirements outside the United States, which are FDA requirements for ensuring product quality control. Our contract manufacturers are subject to continual review and periodic inspections to assess compliance with cGMP. Accordingly, although we are not involved in the day-to-day operations of our contract manufacturers, we are ultimately responsible for ensuring that our products and product candidates are manufactured in accordance with cGMPs. Therefore, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, quality control and quality assurance. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or approved products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our medicines and harm our business and results of operations.

Any performance failure on the part of our existing or future manufacturers, or any interruption or poor yield or quality of manufactured materials, could delay development or marketing approval. We do not currently have arrangements in place for redundant supply. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement.

If our third-party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Thus, our current and anticipated future dependence upon others for the manufacture of our product candidates or medicines may adversely affect our development timeline, our future profit margins or our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

Our product candidates may cause undesirable side effects or have other properties that could halt their development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

We have just begun testing PNT737 in humans and we have not tested PNT141 in humans. It is possible that the FDA or foreign regulatory authorities may not agree with any future assessment of the safety profile of our product candidates. Undesirable side effects caused by any of our product candidates could cause us, IRBs, our CROs, the FDA or foreign regulatory authorities to interrupt, delay or discontinue development and could result in the denial of regulatory approval by the FDA or foreign regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing our product candidates and generating revenues from their sale. In addition, if any of our products cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of this product;
- we may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease;
- our reputation may suffer generally both among clinicians and patients;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy (REMS) in connection with approval, if any; or
- we may be required to change the way the product is administered or conduct additional preclinical studies or clinical trials.

If preliminary data demonstrate that either of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate.

Any one or a combination of these events could prevent us from obtaining approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

We will rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We will depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical studies and clinical trials. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our preclinical studies and clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices (cGCPs), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the data generated in our studies and trials may be deemed unreliable and the FDA or foreign regulatory authorities may require us to perform additional studies or trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our studies or trials comply with the cGCP regulations. In addition, our studies and trials must be conducted with drug product produced under cGMPs. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat studies or trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our preclinical studies and clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons, our studies and trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive or the trials are not well designed.

Regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Clinical trials must be conducted in accordance with cGCPs, or other applicable foreign regulatory authority guidelines. Clinical trials are subject to oversight by the FDA, foreign regulatory authorities and IRBs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable cGMPs. Clinical trials may be suspended by the FDA, foreign regulatory authorities, or us for various reasons, including:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial design necessary to demonstrate efficacy;
- fatalities or other adverse events (AEs) arising during a clinical trial due to medical problems that may or may not be related to clinical trial treatments;
- the product candidate may not appear to be more effective than current therapies; or
- the quality or stability of the product candidate may fall below acceptable standards.

Although we have never been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial, if we elect or are forced to suspend or terminate a clinical trial of any other of our product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

Our efforts to acquire additional product candidates and grow our pipeline may be unsuccessful.

We are currently focused on building a pipeline of additional oncology assets. The identification, evaluation and potential acquisition of additional product candidates is expensive and time-consuming, and our efforts may not lead to the acquisition of any additional product candidates that can be successfully developed and commercialized. If our efforts do not lead to the acquisition of suitable product candidates, we may be unable to grow our pipeline.

Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, they may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

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

The oncology industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We may face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions and governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing therapies that are available for the indication or indications for which they are approved and new therapies that may become available in the future.

There are currently no approved drugs that specifically target Chk1. Genentech is conducting a Phase 1 clinical trial of an oral Chk1 inhibitor in patients with refractory solid tumors or lymphoma. Eli Lilly and Company is developing an intravenous Chk1 inhibitor in several clinical settings, the most advanced of which is in a Phase 2 clinical trial. There are also a number of preclinical programs focused on developing Chk1 inhibitors.

Additionally, there are currently no therapeutics approved as Cdc7 inhibitors that would be direct competitors to PNT141. Takeda Pharmaceutical Company is currently conducting clinical trials of a Cdc7 inhibitor and other companies may be conducting preclinical studies of Cdc7 inhibitors.

Many of the companies against which we may compete have significantly greater financial and other resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the oncology industry may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if any competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain FDA or foreign regulatory approval for their product candidates more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic drugs. If we fail to complete effectively, our business and operating results would be harmed.

We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. If one of our product candidates is approved for sale, we intend to develop an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other oncology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We cannot guarantee that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

We are dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

Our ability to compete in the highly competitive oncology industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are dependent on our management, scientific and medical personnel, including Nick Glover, Ph.D., our President and Chief Executive Officer, Angie You, Ph.D., our Chief Business and Strategy Officer and Head of Commercial, Barbara Klencke, M.D., our Chief Development Officer, and Sukhi Jagpal, our Chief Financial Officer. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business.

Our operations are primarily conducted in Vancouver, British Columbia and near San Francisco, California. Many other oncology companies and many academic and research institutions have located their headquarters in these regions. Competition for skilled personnel in these markets is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

We may form or seek strategic alliances or collaborations in the future. We may be unable to form or enter into such alliances or collaboration arrangements, and we may not realize the expected benefits of any such transaction.

We may form or seek strategic alliances, create joint ventures or collaborations with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may acquire or develop. Any of these transactions and relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. These transactions and relationships also may result in a delay in the development of our product candidates if we become dependent upon the other party and such other party does not prioritize the development of our product candidates relative to its other development activities. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because our product candidates may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that would justify such transaction.

We depend on our information technology and infrastructure.

We rely on the efficient and uninterrupted operation of information technology systems to manage our operations, to process, transmit and store electronic and financial information, and to comply with regulatory, legal and tax requirements. We also depend on our information technology infrastructure for electronic communications among our personnel, contractors, consultants and vendors. System failures or outages could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

In addition, we depend on third parties and applications on virtualized (cloud) infrastructure to operate and support our information systems. These third parties vary from multi-disciplined to boutique providers. Failure by these providers to adequately deliver the contracted services could have an adverse effect on our business, which in turn may materially adversely affect our operating results and financial condition. All information systems, despite implementation of security measures, are vulnerable to disability, failures or unauthorized access. If our information systems were to fail or be breached, such failure or breach could materially adversely affect our ability to perform critical business functions and sensitive and confidential data could be compromised.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from completed or future preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on other third parties for the manufacture of our product candidates and to conduct studies and trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

We may be unable to adequately protect our information technology systems from cyber-attacks, which could result in the disclosure of confidential information, damage our reputation, and subject us to significant financial and legal exposure.

Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include wrongful conduct by hostile foreign governments, industrial espionage, the deployment of harmful malware, denial-of-service, and other means to threaten data confidentiality, integrity and availability. A successful cyber-attack could cause serious negative consequences for our company, including the disruption of operations, the misappropriation of confidential business information and trade secrets, and the disclosure of corporate strategic plans. To date, we have not experienced threats to our data and information technology systems. However, although we devote resources to protect our information technology systems, we realize that cyber-attacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal or reputational harm to us, or would have a material adverse effect on our operating results and financial condition.

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

Our operations, and those of our CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Our corporate headquarters are in Vancouver, British Columbia, and we have an office in Brisbane, California, each of which are near major earthquake faults. Our operations and financial condition could suffer in the event of a major earthquake or other natural disaster.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by such individuals could include intentional failures to comply with FDA or international regulations, provide accurate information to the FDA or foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data timely, completely and accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by third parties could also involve the improper use of information obtained in the course of clinical trials.

We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

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

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management’s time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate; and
- a decline in our stock price.

We currently hold liability insurance coverage, but that coverage may not be adequate to cover any and all liabilities that we may incur. We would need to increase our insurance coverage when we begin the commercialization of our product candidates, if ever. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

As of December 31, 2015, we had U.S. federal operating loss carryforwards of $57.0 million and state operating loss carryforwards of $54.5 million, expiring in years ranging from 2021 to 2035. We also had net tax credit carryforwards of $1.9 million available to reduce future tax liabilities, if any, for U.S. federal purposes. The net tax credit carryforwards begin to expire in 2031. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change," the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes, such as research tax credits, to offset its post-change income and taxes may be limited. In general, an "ownership change" generally occurs if there is a cumulative change in our ownership by "5% stockholders" that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We have experienced an ownership change in the past and may experience ownership changes in the future as a result of future transactions in our stock, some of which may be outside our control. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards, or other pre-change tax attributes, to offset U.S. federal and state taxable income and taxes may be subject to limitations.

We are a U.S.-based multinational company subject to tax in certain U.S. and foreign tax jurisdictions. United States federal, state and local, as well as international tax laws and regulations are extremely complex and subject to varying interpretations. Although we believe that our tax estimates and tax positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities or that we would be successful in any such challenge. If we are unsuccessful in such a challenge, the relevant tax authorities may assess additional taxes, which could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position.

Unstable market and economic conditions may have adverse consequences on our business, financial condition and stock price.

Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy and stock price may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our quarterly operating results may fluctuate significantly, which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to our product candidates or future development programs;
- results of preclinical studies and clinical trials, or the addition or termination of preclinical studies, clinical trials or funding support;
- the timing of the release of results from any preclinical studies and clinical trials;
- the timing and amount of milestone and royalty payments to our licensor;
- our execution of any new collaboration, licensing or similar arrangement, and the timing of payments we may make or receive under such existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, market acceptance and demand for such product candidates;

- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions.

If our quarterly operating results or expected results from development of our product candidates fall outside the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

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

We are currently 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. For example, on November 9, 2016, a purported securities class action lawsuit was filed in the United States District Court for the Southern District of New York against us and certain of our executive officers. The lawsuit was brought by purported stockholders of our company seeking to represent a class consisting of stockholders who purchased stock between July 15, 2015 and June 6, 2016. The lawsuit asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and seeks unspecified damages and other relief. We are generally obliged, to the extent permitted by law, to indemnify our executive officers who are named as defendants in these types of lawsuits. Regardless of the outcome, this or 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 Government Regulation

We may be unable to obtain U.S. or foreign regulatory approval of our product candidates, and, as a result, we may be unable to commercialize our product candidates.

Our product candidates are, and any future product candidates that we may develop will be, subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, import, export, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing, distribution, import and export of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be successfully completed before a new drug can be marketed in the United States and in many foreign jurisdictions. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop will obtain the regulatory approvals necessary for us or our collaborators to begin selling them.

Approval of our product candidates will involve preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the product candidate for each indication for which FDA approval is sought. The preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The results of our preclinical testing are required to be submitted to the FDA as part of our IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans.

After submission of a NDA, the FDA may refuse to file the application, deny approval of the application, require additional testing or data or, if the NDA is filed and later approved, require post-marketing testing and surveillance to monitor the safety or efficacy of a product. Under the Prescription Drug User Fee Act (PDUFA), the FDA has agreed to certain performance goals in the review of NDAs. The FDA's timelines are flexible and subject to change based on workload and other potential review issues and may delay the FDA's review of an NDA. Further, the terms of approval of any NDA, including the product labeling, may be more restrictive than we desire and could affect the marketability of our products.

As a company, we have very limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA or foreign regulatory authorities, and, as a company, we have no experience in obtaining approval of any product candidates. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the initiation of clinical trials, depending upon the type, complexity and novelty of the product candidate. We may encounter delays or rejections during any stage of the regulatory review and approval process based upon the failure of clinical or laboratory data to demonstrate compliance with, or upon the failure of the product candidates to meet, the FDA's or foreign regulatory authorities' requirements for safety, efficacy and quality.

The standards that the FDA and foreign regulatory authorities use when regulating us are not always applied predictably or uniformly and can change. Because the product candidates we are developing may represent a new class of drug, the FDA and foreign regulatory authorities have not yet established any definitive policies, practices or guidelines in relation to these drugs. The lack of policies, practices or guidelines may hinder or slow review by the FDA or foreign regulatory authorities of any regulatory filings that we may submit. Moreover, the FDA or foreign regulatory authorities may respond to these submissions by defining requirements we may not have anticipated. Such responses could lead to significant delays in the development of our product candidates.

Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations, for example, from future legislation or administrative action, or from changes in FDA or foreign regulatory authority policy during the period of product development, clinical trials and regulatory review. It is impossible to predict whether legislative changes will be enacted, or whether FDA or foreign regulatory authority, guidance or interpretations will be changed, or what the impact of such changes, if any, may be.

In addition, the FDA and foreign regulatory authorities may delay, limit, or deny approval of a product candidate for many reasons, including:

- disagreement with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or foreign regulatory authorities that a product candidate is safe and effective for any indication;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the results of our clinical trials may not demonstrate the safety or efficacy required by the FDA or foreign regulatory authorities for approval;
- the FDA or foreign regulatory authorities may find deficiencies in our manufacturing processes or facilities; and
- the FDA's or foreign regulatory authorities' approval policies or regulations may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we comply with all of the regulatory requirements of the FDA and foreign regulatory authorities, we may not obtain regulatory approval for any of our product candidates in development. If we fail to obtain regulatory approval for any of our product candidates in development, we will have fewer commercialized products than we anticipate and correspondingly lower revenue.

In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs, and the FDA's standards, especially regarding drug safety, appear to have become more stringent.

Any delay or failure in obtaining required approvals could have a material adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS plan as part of or after approval, which may impose further requirements or restrictions on the distribution or use of an approved product, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may limit the size of the market for the product and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

If we or any collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

- adverse regulatory inspection findings;
- warning letters;
- voluntary or mandatory product recalls or public notification or medical product safety alerts to healthcare professionals;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on, or prohibitions against, importation or exportation of our products;
- suspension of review or refusal to approve pending applications or supplements to approved applications;

- exclusion from participation in government-funded healthcare programs;
- exclusion from eligibility for the award of government contracts for our products;
- suspension or withdrawal of product approvals;
- product seizures;
- injunctions; and
- civil and criminal penalties and fines.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate, and may require us to conduct post-approval clinical studies. The FDA may also require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, AE reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval.

Moreover, if we obtain regulatory approval for our product candidates, we will only be permitted to market our products for the indication approved by FDA or foreign regulatory authority, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products, or otherwise not permit labeling that sufficiently differentiates our product candidates from competitive products with comparable therapeutic profiles. For example, we will not be able to claim that our products have fewer side effects, or improve compliance or efficacy unless we can demonstrate those attributes to FDA or foreign regulatory authority in comparative clinical trials.

Later discovery of previously unknown problems with our product candidates, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal by the FDA or foreign regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions, the imposition of civil penalties or criminal prosecution.

The FDA's and foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

If we or any of our independent contractors, consultants, collaborators, manufacturers, vendors or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions, which could result in penalties and affect our ability to develop, market and sell our product candidates and may harm our reputation.

We are or may in the future be subject to federal, state, and foreign healthcare laws and regulations pertaining to, among other things, fraud and abuse and patients' rights. These laws and regulations include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made under a federal healthcare program such as Medicare or Medicaid;
- the U.S. federal false claims and civil monetary penalties laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting or causing to be presented, claims for payment by government funded programs such as Medicare or Medicaid that are false or fraudulent, and which may apply to us by virtue of statements and representations made to customers or third parties;
- the U.S. federal Health Insurance Portability and Accountability Act (HIPAA), which created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing or attempting to execute a scheme to defraud healthcare programs;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), which imposes requirements on certain types of people and entities relating to the privacy, security, and transmission of individually identifiable health information, and requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the federal Physician Payment Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, to report annually to the Centers for Medicare & Medicaid Services (CMS) information related to payments and other transfers of value to physicians, other healthcare providers and teaching hospitals, and ownership and investment interests held by physicians and other healthcare providers and their immediate family members, which is published in a searchable form on an annual basis; and
- state laws comparable to each of the above federal laws, such as, for example, anti-kickback and false claims laws that may be broader in scope and also apply to commercial insurers and other non-federal payors, requirements for mandatory corporate regulatory compliance programs, and laws relating to patient data privacy and security. Other state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If our operations are found to be in violation of any such health care laws and regulations, we may be subject to penalties, including administrative, civil and criminal penalties, monetary damages, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or foreign regulatory authorities, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Any products we develop may become subject to unfavorable pricing regulations, third-party coverage and reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Many countries require approval of the sale price of a drug before it can be marketed. The pricing review period begins after marketing or product licensing approval is granted in most cases. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Although we intend to monitor these regulations, our programs are currently in the early stages of development and we will not be able to assess the impact of price regulations for a number of years. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. In many jurisdictions, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. Obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. If we are not currently capturing the scientific and clinical data that will be required for reimbursement approval, we may be required to conduct additional trials, which may delay or suspend reimbursement approval. Additionally, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in the early stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of reimbursement. Increasingly, the third-party payors, such as government and private insurance plans, who reimburse patients or healthcare providers, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for pharmaceutical products. If the coverage provided for any products we develop is inadequate in light of our development and other costs, our return on investment could be adversely affected.

Certain products we develop may need to be administered under the supervision of a physician on an outpatient basis. Under applicable U.S. law, certain drugs that are not usually self-administered (including certain injectable drugs) may be eligible for coverage under the Medicare Part B program if:

- they are incident to a physician’s services;
- they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and
- they have been approved by the FDA and meet other requirements of the statute.

There may be significant delays in obtaining coverage for newly-approved products, and coverage may be more limited than the purposes for which the drug is approved by the FDA or foreign regulatory authorities. Moreover, eligibility for coverage does not imply that any drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent.

Reimbursement may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition.

We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare and legislative and regulatory proposals to broaden the availability of healthcare will continue to affect the business and financial condition of oncology companies. A number of legislative and regulatory changes in the healthcare system in the United States and other major healthcare markets have been proposed in recent years, and such efforts have expanded substantially in recent years. These developments have included prescription drug benefit legislation that was enacted and took effect in January 2006, healthcare reform legislation enacted by certain states, and major healthcare reform legislation that was passed by Congress and enacted into law in the United States in 2010. These developments could, directly or indirectly, affect our ability to sell our products, if approved, at a favorable price.

For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act (PPACA), contains provisions that affect companies in the pharmaceutical industry and other healthcare related industries by imposing additional costs and changes to business practices. Provisions affecting pharmaceutical companies include the following.

- mandatory rebates for drugs sold into the Medicaid program were increased, and the rebate requirement was extended to drugs used in risk-based Medicaid managed care plans;
- the 340B Drug Pricing Program under the Public Health Services Act was extended to require mandatory discounts for drug products sold to certain critical access hospitals, cancer hospitals and other covered entities;
- expansion of eligibility criteria for Medicaid programs;
- expansion of entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the “donut hole”; and
- pharmaceutical companies are required to pay an annual non-tax deductible fee to the federal government based on each company’s market share of prior year total sales of branded products to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense. Since we expect our branded pharmaceutical sales, if any of our products are approved, to constitute a small portion of the total federal health program pharmaceutical market, we do not expect this annual assessment to have a material impact on our financial condition.

There have been judicial and Congressional challenges, and amendments to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. The full effect of the U.S. healthcare reform legislation on our business activities is unknown. The financial impact of the U.S. healthcare reform legislation will depend on a number of factors, including but not limited to, the policies reflected in implementing regulations and guidance and changes in sales volumes for products affected by the new system of rebates, discounts and fees. The legislation may also have a positive impact on our future net sales, if any, by increasing the aggregate number of persons with healthcare coverage in the United States. Further, new litigation is currently pending before the U.S. Supreme Court to invalidate certain provisions of the PPACA.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

Our ability to obtain services, reimbursement or funding from the federal government may be impacted by possible reductions in federal spending.

U.S. federal government agencies currently face potentially significant spending reductions. Under the Budget Control Act of 2011, the failure of Congress to enact deficit reduction measures of at least $1.2 trillion for the years 2013 through 2021 triggered automatic cuts to most federal programs. These cuts would include aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, which was enacted on January 1, 2013, among other things, reduced Medicare payments to several providers, including hospitals and imaging centers. The full impact on our business of these automatic cuts is uncertain. If federal spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Obtaining and maintaining regulatory approval for our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of any of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval for our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval for a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve

requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by ourselves and our third-party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States and abroad governing laboratory procedures and the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental, health and safety laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

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

Risks Related to Our Intellectual Property

We depend on intellectual property licensed from CPF and Carna, and the termination of these licenses could result in the loss of significant rights, which would harm our business.

Pursuant to a license agreement with CPF, we hold an exclusive license from CPF to use certain patented technology, including certain patent rights, know-how and materials related to the Chk1 inhibitor cancer drug candidate. Either party may terminate the agreement if the other party materially breaches the agreement, subject to certain cure provisions, and CPF may terminate the agreement in certain limited circumstances. We may also terminate the agreement at any time upon 90 days' prior written notice to CPF. Additionally, pursuant to a license agreement with Carna Biosciences, Inc. (Carna), we hold an exclusive license from Carna to use certain patented technology, including certain patent rights and know-how related to Cdc7 kinase inhibitors. Carna may terminate the agreement in the event of our material breach, subject to certain cure provisions, and we may terminate the agreement at any time upon 30 days' prior written notice to Carna.

Disputes may arise between us and our licensors regarding intellectual property subject to these license agreements, including with respect to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the amount and timing of milestone and royalty payments;
- the rights of our licensors under the license agreements;

- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

Any disputes with our licensors over intellectual property that we have licensed from them may prevent or impair our ability to maintain our current licensing arrangements. We depend on these licensed technologies and products to develop our product candidates. Termination of our license agreements could result in the loss of significant rights and could materially harm our ability to further develop and commercialize our product candidates.

If we are not able to obtain and enforce patent protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. Our licensors have filed, and we will continue to file, patent applications directed to the compositions of matter and methods of use related to various aspects of our product candidates.

We and our current or future licensors and licenses may not be able to apply for or prosecute patents on certain aspects of our product candidates or technologies at a reasonable cost in a timely fashion or at all. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If our current licensors, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition and operating results.

There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our issued or granted patents will not later be found to be invalid or unenforceable or that any issued or granted patents will include claims that are sufficiently broad to cover our product candidates or technologies or to provide meaningful protection from our competitors. Moreover, the patent position of oncology companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely impact our position in the market.

The U.S. Patent and Trademark Office (USPTO) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in oncology patents. Moreover, changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. While we will endeavor to try to protect our product candidates with intellectual property rights such as patents, as appropriate, the process of obtaining patents is time-consuming, expensive and sometimes unpredictable.

Further, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed (or 20 years after the filing date of the first non-provisional US patent application to which it claims priority). Various extensions may be available; however the life of a patent, and the protection it affords, is limited. Without patent protection for our product candidates, we may be open to competition from generic versions of our product candidates. Further, the extensive period of time between patent filing and regulatory approval for a product candidate limits the time during which we can market a product candidate under patent protection, which may particularly affect the profitability of our early-stage product candidates.

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

In addition to seeking patent protection for certain aspects of our product candidates and technologies, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us.

Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

Numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the Leahy-Smith America Invents Act (AIA) enacted in 2011 involves significant changes in patent legislation. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

Further, the Supreme Court has ruled on several patent cases in recent years, some of which cases either narrow the scope of patent protection available in certain circumstances or weaken the rights of patent owners in certain situations. These changes have led to increasing uncertainty with regard to the scope and value of our issued patents and to our ability to obtain patents in the future.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that may weaken our and our licensors’ ability to obtain new patents or to enforce existing patents we and our licensors or partners may obtain in the future.

Once granted, patents may remain open to opposition, interference, re-examination, post-grant review, inter partes review, nullification derivation and opposition proceedings in court or before patent offices or similar proceedings for a given period after allowance or grant, during which time third parties can raise objections against such initial grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether.

We, our licensors or any future strategic partners may become subject to third-party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights.

We, our licensors or any future strategic partners may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights that prevent us from developing and commercializing our products. If we, our licensors or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay substantial damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. In addition, we, our licensors or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products or certain aspects of our platform technology. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

In addition, in an infringement proceeding, a court may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

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

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to oncology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates and technologies or we could lose certain rights to grant sublicenses.

Our current license agreements impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement, and other obligations on us. For example, we are required to pay CPF and Carna milestone payments in an aggregate amount of up to $319.5 and $270 million, respectively, based upon the achievement of certain developmental, regulatory and commercial milestones of PNT737 and PNT141. We are also required to pay CPF tiered high single-digit to low double-digit royalties on the net sales of PNT737 and to pay Carna tiered single-digit royalties on the net sales of PNT141. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, we may be required to pay significant milestone and royalty payments, depending on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

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

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other oncology companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

Risks Related to Ownership of Our Common Stock

The market price of our common stock has been and may continue to be volatile, and you may be unable to sell your shares at or above the price at which you purchased them.

The market price of our common stock may be subject to wide fluctuations. For example, we experienced a significant decrease in our stock price after we announced the suspension of the development of PNT2258 and the DNAi platform in June 2016. Factors affecting the market price of our common stock include:

- the timing and results of development activities related to our product candidates;
- our ability to acquire or in-license new product candidates to grow our pipeline;
- the commencement, enrollment or results of future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- disputes with CPF or Carna regarding our licensed technology and products;
- adverse results or delays in preclinical studies or clinical trials;
- changes in laws or regulations applicable to our product candidates, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and oncology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act (JOBS Act) enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 (Section 404) of the Sarbanes-Oxley Act of 2002, as amended (Sarbanes-Oxley Act), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, are subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, changes in rules of U.S. generally accepted accounting principles or their interpretation, the adoption of new guidance or the application of existing guidance to changes in our business could significantly affect our financial position and results of operations.

We incur significantly increased costs and devote substantial management time as a result of operating as a public company.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the stock exchange upon which our common stock is listed and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are not currently required to comply with the rules of the Securities and Exchange Commission (SEC) that implement Section 404, and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose until our annual report for the year ended December 31, 2016. Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404.

Additionally, we have in the past and may in the future identify material weaknesses or significant deficiencies in internal control over financial reporting. Under standards established by the Public Company Accounting Oversight Board, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency or combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis. We cannot assure you that there will not be additional material weaknesses or significant deficiencies that our independent registered public accounting firm or we will identify. If we identify such issues or if we are unable to produce accurate and timely financial statements, our stock price may be adversely affected and we may be unable to maintain compliance with the Nasdaq Stock Market listing requirements.

Provisions in our restated certificate of incorporation and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our restated certificate of incorporation and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the securities or industry analysts who publish research about us downgrade our stock or publish inaccurate or unfavorable evaluations of our company or our stock, the price of our stock could decline. If one or more of these analysts cease coverage of our company, our stock may lose visibility in the market, which in turn could cause our stock price to decline.

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

Use of Proceeds

On July 15, 2015, our Registration Statement on Form S-1 (File No. 333-204921) relating to the IPO of our common stock was declared effective by the SEC.

In June 2016, we halted investment in PNT2258, our former lead product candidate, based on our review of the interim results from a Phase 2 trial of PNT2258. Accordingly, we now intend to use the remaining net proceeds from our IPO to advance the development of PNT737, PNT141, acquire or in-license additional product candidates and technologies and for other general corporate purposes.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

SIGNATURES

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

PRONAI THERAPEUTICS, INC.

Date: November 10, 2016

By: /s/ Nick Glover
Dr. Nick Glover
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2016

By: /s/ Sukhi Jagpal
Sukhi Jagpal
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit No.	Exhibit Filing Date	
10.1#	License Agreement between CRT Pioneer Fund LP and ProNAi Therapeutics, Inc. dated September 27, 2016.					X
31.1	Certification of Principal Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
31.2	Certification of Principal Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					X
32.1*	Certification of Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
32.2*	Certification of Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					X
101.INS	XBRL Instance Document.					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 Labels Linkbase Document.					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.					X

Portions of this exhibit have been omitted based on an application for confidential treatment submitted to the SEC. The omitted portions of this exhibit have been filed separately with the SEC.

* This certification is deemed not filed for purpose of section 18 of the 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 or the Exchange Act.

EXHIBIT 10.1

[*] **Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.**

EXECUTION VERSION **CONFIDENTIAL**

DATED 27TH SEPTEMBER 2016

(1) CRT PIONEER FUND LP

AND

(2) PRONAI THERAPEUTICS, INC.

Licence Agreement

***Confidential Treatment Requested.**

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THIS LICENCE AGREEMENT is made the 27th day of September 2016

BETWEEN:

(1) **CRT PIONEER FUND LP** (the "**CPF**"), a limited liability partnership established in England and Wales under number LP 14391 with registered office at 4 Claridge Court, Lower Kings Road, Berkhamsted, Hertfordshire, HP4 2AF, acting by its general partner, CRT Pioneer GP Limited, a company registered in England and Wales with registered number 07933818 whose registered office is at 4 Claridge Court, Lower Kings Road, Berkhamsted, Hertfordshire, HP4 2AF (the "**General Partner**"); and

(2) **PRONAI THERAPEUTICS, INC.**, a Delaware corporation with an address at 1000 Marina Blvd, Suite 450, Brisbane, CA 94005, United States ("**ProNAi**").

WHEREAS:

(A) CPF is a limited liability partnership formed pursuant to a limited partnership agreement between the General Partner, the European Investment Fund, CRT (as defined below), BACIT Discovery Limited, and CRT Pioneer CIP LP. The General Partner has the right to enter into legal agreements on behalf of CPF by which CPF is then bound.

(B) The CHK1 Programme arose from a collaboration between ICR, Sareum (each as defined below) and CRT. The collaboration was governed under the terms of an agreement between CRT, ICR and Sareum dated 21 July 2005 and extended by the parties to that agreement by a letter dated 5 October 2007. Under this Agreement, and otherwise, CRT and ICR have rights to commercialise the Intellectual Property arising from the CHK1 Programme.

(C) CPF, ICR and CRT entered into a licence and collaboration agreement dated September 23, 2013 for the onward development and commercialisation of the CHK1 Programme in the Territory, as amended and restated on September 20, 2016, (the "**Upstream Licence Agreement**").

(D) CPF and ProNAi have agreed to enter into a licence for the further development and commercialization of the CHK1 Programme in the Territory (as defined below).

(F) Therefore, CPF and ProNAi have agreed to enter into this licence agreement on the following terms and conditions.

NOW IT IS HEREBY AGREED as follows:

1. INTERPRETATION

1.1 In this Agreement except where the context requires otherwise, the following words and expressions shall have the following meanings:

"Active Party" shall have the meaning given in Clause 8.9(c).

"Additional CPF Intellectual Property" shall have the meaning given in Clause 3.1.1.

"Affiliate" shall mean, with respect to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with, such Person. A Person shall be regarded as in control of another Person if it owns, or directly or indirectly controls, at least fifty percent (50%) of the voting stock or other ownership interest of the other Person, or if it directly or indirectly possesses the power to direct or cause the direction of the management and policies of the other Person by any means whatsoever.

"Affordable" means in relation to a Licensed Product: (i) a determination by the UK Pricing Authority that such Licensed Product should be used within the National Health Service (or any successor); and/or (ii) approval by the UK Pricing Authority of the price proposed by ProNAi or its Sub-Licensee in relation to sales of that Licensed Product in the United Kingdom (or one or more constituent countries thereof).

"Agreement" means this agreement and each of the Schedules as amended from time to time in accordance with Clause 19.

"Arising Intellectual Property" means all Materials and Know How (other than that comprised in Licensed Intellectual Property) conceived or generated after the Effective Date by or on behalf of ProNAi in the course of exercising the licence rights granted under Clause 3.1; and any Patent rights owned by ProNAi as a direct result of exercising the licence rights granted under Clause 3.1 which claim any such Materials and/or inventions described or comprised in such Know How.

"Biomarker" means an endogenous characteristic that is objectively measured and evaluated as an indicator or predictor of normal biological or pathogenic processes or pharmacological responses to a therapeutic intervention.

"Business Day" means a day other than a Saturday, Sunday or any public holiday in England, the United States or Canada.

"CHK1 Inhibitor" means a compound which is claimed, even if not specifically exemplified, in a patent comprised in the Licensed Patents.

"CHK1 Clinical SOPs" means the standard operating protocols for the clinical implementation of the assays identified in Schedule 5. For the avoidance of doubt, CHK1 Clinical SOPs are included within Non-Compound Intellectual Property (and does not convey exclusive rights to any Biomarkers used in the relevant assays).

"Clinical Development Plan" means the plan which sets forth a detailed overview of the intended clinical development of each Licensed Product, including without limitation a summary of all material development activities to be conducted by or on behalf of ProNAi for the purposes of obtaining Regulatory Approval for Licensed Products in the Territory, together with associated timelines for such activities. An exemplary Clinical Development Plan has been prepared prior to the Effective Date and appended at Schedule 9. The Clinical Development Plan shall be updated at least annually by ProNAi and details of any material updates shall be set forth in the next applicable Progress Report and provided to CPF in accordance with Clause 4.4.1.

"Combination Product" has the meaning given in the definition of "Net Sales".

"Commencement" means, in relation to a clinical trial, the date upon which administration of a Licensed Product to the first human subject has occurred, whether such subject is a healthy volunteer or a patient.

"Commercially Reasonable Efforts" means (a) with respect to CPF's efforts, the efforts and resources commonly used by a virtual biotechnology company with respect to the prosecution and maintenance of Intellectual Property rights and the development of a compound or product of similar potential at a similar stage in its lifecycle; or (b) with respect

to ProNAi's efforts, the efforts and resources commonly used by a drug development company of similar size, remit and resources as ProNAi, for a product at a similar stage in its life cycle, with the objective of developing such product in a diligent and timely manner, taking into consideration its safety, efficacy, the Patent or other proprietary position the competitiveness of the marketplace, the regulatory structure involved, and the absolute profitability of the product (without reference to any other products being developed or commercialized by or on behalf of ProNAi or its Affiliates).

"**Competent Authority"** means any local or national agency, court, authority, department, inspectorate, minister, ministry official or public or statutory person (whether autonomous or not) of, or of any government of, any country having jurisdiction over the Agreement or either of the Parties (such as the Financial Services Authority or any successor entity) or over the development or marketing of medicinal products (such as the FDA, the EMA and the MHLW).

"Compound Intellectual Property" means any Licensed Intellectual Property to the extent; that it is (i) a CHK1 Inhibitor; or (ii) directly related to CHK1 Inhibitors including their use in the Field. For the avoidance of doubt Compound Intellectual Property excludes Exclusive Biomarkers.

"Confidential Information" means any information, in tangible or non-tangible form (including oral disclosure) including Know How, research and development plans, information relating to the customers, suppliers, business partners, clients, finances, business plans and products (in each case actual or prospective) of a Party, the terms of this Agreement, and any other technical or business information (whether or not marked as confidential), which is obtained by either Party from the other (or its Representatives) pursuant to this Agreement.

"Control" means, as the context requires, with respect to any item of Intellectual Property or right under any Intellectual Property, the possession by a Party (whether by ownership or license, other than pursuant to this Agreement) of the ability to grant access (by licence or sublicense), without violating the terms of any agreement or other arrangement with any Third Party existing at the time.

"CPF Indemnified Parties" means (a) CPF and its respective officers, employees and agents, and (b) CRT, CRUK, ICR and their respective officers, employees and agents.

"CPF Indemnitees" shall have the meaning given in Clause 8.9.

"CPF In-Licence" means all agreements (as modified, amended or restated as of the Effective Date), pursuant to which CPF or its Affiliates derive any right, title or interest in or to the Licensed Intellectual Property, including without limitation the Upstream Licence Agreement.

"CPF Reviewers" means:

(a) independent persons nominated by CPF for the purpose of monitoring and reviewing work and/or providing scientific advice; and

(b) as contemplated by Clause 17.2, any actual or potential royalty purchaser.

"CRT" means Cancer Research Technology Limited, a company registered in England and Wales under number 1626049 with registered office at Angel Building, 407 St John Street, London, EC1V 4AD, England.

"CRUK" means Cancer Research UK, a company limited by guarantee (registered in England and Wales under number 4325234) and a charity (registered in England under number 1089464 and registered in Scotland under number SC041666 and in the Isle of Man under number 1103) of Angel Building, 407 St John Street, London, EC1V 4AD, United Kingdom.

"CTA" means Clinical Trial Authorisations.

"Disclosing Party" shall have the meaning given in Clause 13.1.

"**Effective Date"** means the date this Agreement is made.

"EMA" means the European Medicines Agency for the Evaluation of Medicinal Products of the European Union, or the successor thereto.

"Exclusive Biomarkers" means all Biomarkers which function as a diagnostic or efficacy or prognostic marker exclusively for use in conjunction with a Licensed Product. For the sake of

clarity, Exclusive Biomarkers excludes any Biomarker which functions (to any reasonably measurable degree) as a diagnostic, efficacy or prognostic marker in relation to any compound which is not a CHK1 Inhibitor, a class of compounds or more than one molecular target.

"Executive Officers" means a managing partner of CPF, and the Chief Executive Officer of ProNAi, or in each case such other authorised officer of a Party as may be substituted from time to time upon the giving of written notice to the other Party.

"**Expert"** means a suitably qualified independent expert appointed by agreement between the Parties. However, in the event that the Parties are unable to reach agreement within fifteen (15) Business Days of CPF on the one hand and ProNAi on the other seeking in writing to the other to appoint such expert, each Party shall submit two (2) names to the [*] (or any successor body thereto), who shall select an individual from the names submitted.

"Extended Exclusivity Period" means, on a country-by-country and Licensed Product-by-Licensed Product basis, the later of:

i. any period during which one of the following subsists in respect of a Licensed Product: Orphan Drug Designation, paediatric designation or other exclusivity (excluding a Patent) granted by a Competent Authority beyond the expiry of the relevant Patent; or

ii. the expiry of [*] years from the date of the First Commercial Sale of that Licensed Product (or former Licensed Product) in the relevant country by ProNAi or a Sub-Licensee on arm's length terms.

"FDA" means the United States Food and Drug Administration or any successor to it.

"**Field"** means the treatment, prophylaxis and/or diagnosis of any disease, state or condition.

"First Commercial Sale" means, with respect to a Licensed Product, the first transfer or disposition for value of such Licensed Product to a Third Party, after all relevant Registrations for the transfer or disposition of such Licensed Product have been obtained in respect of the relevant region or country.

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"Force Majeure" means in relation to either Party any event or circumstance which is beyond the reasonable control of that Party, which event or circumstance that Party could not reasonably be expected to have taken into account at the Effective Date and which results in or causes the failure of that Party to perform any or all of its obligations under this Agreement including act of God, lightning, fire, storm, flood, earthquake, strike, lockout or other industrial disturbance, war, terrorist act, blockade, revolution, riot, insurrection, civil commotion, public demonstration, sabotage, act of vandalism, explosion, provided that lack of funds shall not be interpreted as a cause beyond the reasonable control of that Party.

"Generic Competition" means with respect to a Licensed Product in any particular country in the Territory, the existence on the market of any Generic Product in competition with such Licensed Product in such country.

"Generic Product" means any pharmaceutical product that: (a) is sold by a Third Party other than pursuant to any rights granted by ProNAi; and (b) contains the same active pharmaceutical ingredient (or one which is substantially the same or bioequivalent, such as a hydrate or salt of the active pharmaceutical ingredient) as the Licensed Product; and (c) was granted pursuant to an application for a marketing authorisation that relies on data held by a regulatory authority in relation to a Licensed Product.

"ICR" means the Institute of Cancer Research: Royal Cancer Hospital, a company limited by guarantee (Company number 00534147) a college of the University of London and a charity exempt from registration with registered office at 123 Old Brompton Road, London SW7 3RP, England.

"Inactive Parties" shall have the meaning given in Clause 8.9(c).

"IND" means an investigational new drug application filed with the FDA necessary to commence human clinical trials.

"Indemnitee" shall have the meaning given in Clause 10.3.

"Indemnitor" shall have the meaning given in Clause 10.3.

"Indication" means a disease classification as defined within the 'International Statistical Classification of Diseases and Related Health Problems' as published from time to time by

the World Health Organization (e.g. “C50 Malignant neoplasm of Breast”, “C92 Myeloid leukaemia”, “B20 Human immunodeficiency virus [HIV] disease resulting in infectious and parasitic diseases” and “M34 Systemic sclerosis”).

“Infringement Action” shall have the meaning given in Clause 8.7.

“Innocent Parties” shall have the meaning given in Clause 16.1.

“Intellectual Property” means Materials, Patents and Know How.

“Key Activity” means any of the following in relation to a Licensed Product:

i. significant research activity related to biological processes that a Licensed Product would or could affect, including, but not limited to, animal studies;

ii. active preclinical work required for any contemplated clinical trial, including any toxicology or pharmacokinetic work;

iii. active planning of a clinical trial (or in the event of issues arising with a Competent Authority in relation to a clinical trial, active negotiation with such Competent Authority and/or replanning of the clinical trial);

iv. actively seeking to obtain the necessary IND, other regulatory approvals or other approvals to carry out a clinical trial;

v. active enrolment of patients into, or participation of patients in, a clinical trial, where relevant in accordance with the protocol in order to determine if the primary end point has been met;

vi. active monitoring, analysis or reporting on the data arising from a clinical trial where relevant in accordance with the protocol in order to determine if the primary end point has been met;

vii. manufacture or formulation of a Licensed Product for use in a clinical trial, including active process development work in support of planned manufacture; and

viii. preparation for and making submissions to regulatory agencies for an NDA or awaiting the outcome of such submission.

"Know How" means technical and other information which is not in the public domain including, ideas, concepts, inventions, discoveries, data, formulae, algorithms, specifications, clinical data, information relating to Materials (including biological and chemical structures and functions as well as methods for synthesising chemical compounds), procedures for experiments and tests, results of experimentation and testing, results of research and development including laboratory records and data analyses. Information in a compilation or a compilation of information may be Know How notwithstanding that some or all of its individual elements are in the public domain.

"Licensed Compound" means any CHK1 Inhibitor that is claimed in a Patent comprised in the Licensed Intellectual Property.

"**Licensed Intellectual Property**" means the Licensed Patents, Licensed Know-How, Licensed Materials and any Intellectual Property which CPF Controls pursuant to the MTAs.

"Licensed Know How" means Know How Controlled by CPF which is (a) in existence at the Effective Date or (b) that is disclosed to ProNAi by CPF or its Affiliates during the Term and which is directly related to CHK1 Inhibitors. An exemplary list of Licensed Know How is described on Schedule 2. Licensed Know-How will include any Know-How Controlled by CPF that is (i) created by or on behalf of CPF or any Affiliate after the Effective Date as a result of CPF's conduct of activities in relation to the Phase I Clinical Trials of CCT245737 prior to the transfer to ProNAi of the Product CTAs, or (ii) generated under, and provided to CPF pursuant to, the MTAs, to the extent directly related to CHK1 Inhibitors.

"Licensed Materials" means the Materials in existence at the Effective Date and which are: (a) CHK1 Inhibitors first synthesised at ICR's Cancer Therapeutics Unit (whether or not specifically exemplified in a Licensed Patent); and (b) described in Schedule 3. To the extent that any Non-Compound Materials exist at the date of this Agreement which: (i) relate to the Licensed Know How; and (ii) are not reasonably available from stock from a commercial supplier; and (iii) after the Effective Date, ProNAi reasonably requests for use by it or a Sub-Licensee in the further development and commercialisation of the CHK1 Inhibitors licensed under this Agreement; and (iv) are available at the time of the request, then Schedule 3 and this definition shall be amended and said Materials will be provided to ProNAi at no cost.

"Licensed Patents" means: (i) the Patents set out in Schedule 1 and any Patents claiming priority therefrom, or common priority thereto, whether or not in existence at the Effective Date; (ii) any Patents filed by or in the name of CPF or its Affiliates, CRT or ICR on or after the Effective Date claiming any part of the Licensed Materials or their manufacture or use and/or Licensed Know-How; (iii) any Patents filed by or in the name of CPF or its Affiliates, on or after the Effective Date claiming analogues of Licensed Materials (to the extent that their primary mechanism of action is through inhibition of CHK1, or their manufacture or use, (iv) any Patents filed by or in the name of CRT or ICR, on or after the Effective Date, solely to the extent that CPF is granted rights under such Patents pursuant to the Upstream Licence Agreement, where such Patents claim analogues of Licensed Materials (to the extent that their primary mechanism of action is through inhibition of CHK1) or their manufacture or use,; (v) any Patents claiming priority from the Patents described in (i), (ii), (iii) or (iv).

"Licensed Products" means any product: (i) which falls within the scope of one or more Valid Claims of any of the Licensed Patents in the relevant country or territory; and/or (ii) containing a Licensed Compound and/or (iii) which product was developed using or incorporating any part of the Licensed Intellectual Property, including in each case any metabolites, prodrugs, salts, hydrates, solvates, esters, intermediates, polymorphs, isomers, analogues and derivatives of any Licensed Compounds.

"Major Markets" means the United Kingdom, the United States, France, Italy, Germany, Spain and Japan and "**Major Market**" shall mean any one of them.

"Materials" means any chemical or biological material including any: organic or inorganic element or compound; nucleotide or nucleotide sequence including DNA and RNA sequences; gene; vector or construct including plasmids, phages, bacterial vectors, bacteriophages and viruses; host organism including bacteria, fungi, algae, protozoa and hybridomas; eukaryotic or prokaryotic cell line or expression system or any development strain or product of that cell line or expression system; protein including any peptide or amino acid sequence, enzyme, antibody or protein conferring targeting properties and any fragment of a protein or a peptide enzyme or antibody; drug or pro-drug; assay or reagent; any other genetic or biological material or micro-organism or any transgenic animal; and any physical property rights relating to any of the foregoing.

"MHLW" means the Ministry of Health, Labour and Welfare of Japan, or the successor thereto.

"MHRA" means the Medicines & Healthcare Products Regulatory Agency.

"Milestone Event" has the meaning given in Clause 5.5.

"Milestone Payment" has the meaning given in Clause 5.5.

"MTAs" means the following material transfer agreements put in place to cover the transfer of CHK1 Inhibitors [*].

"NDA" means an application for approval to market a product commercially such as the New Drug Application filed pursuant to the requirements of the FDA, as more fully defined in 21 CFR.§ 314.3 et seq, or a Biologics Licence Application filed pursuant to the requirements of the FDA, as more fully defined in 21 CFR § 601, or a Marketing Authorisation application filed pursuant to the requirements of European Directive 2001/ 83/ EC, or any equivalent or similar application filed with any other Competent Authority in any country or region in the Territory, together, in each case, with all additions, deletions or supplements thereto.

"Net Sales" means the gross amount invoiced by ProNAi, its Affiliates or each of their Sub-Licensee to Third Parties for the sale of Licensed Products to customers who are not Affiliates (or are Affiliates but are the end users of the Licensed Product) in the Territory, less, to the extent deducted from or on such invoice consistent with generally accepted accounting principles, consistently applied, the following items:

i. customary and reasonable trade, quantity, and cash discounts and wholesaler and pharmacy allowances including initial stocking and distribution allowances; provided that, in the case of pharmacy incentive research programs, hospital performance incentive research program chargebacks, disease management research programs, similar research programs or discounts and wholesaler allowances on "bundles" of products, all discounts, wholesaler allowances and the like shall be allocated among

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products on the basis on which such discounts, wholesaler allowances or the like were actually granted or, if such basis cannot be determined, in proportion to the respective list prices of such products;

ii. customary and reasonable credits, rebates chargebacks, and administrative fees (including, but not limited to, those to managed-care entities, pharmacy benefit managers, and government agencies and programs), patient rebates, and discounts, and allowances or credits to customers on account of rejection or returns (including, but not limited to, wholesaler and retailer returns) or affecting such product;

iii. freight, fees for services charges, postage and duties, shipping and insurance charges relating to such product;

iv. sales taxes (such as value added tax or its equivalent) and excise taxes, other consumption taxes, customs duties and compulsory payments to governmental authorities and any other governmental charges imposed upon the importation, use or sale of such product to Third Parties (excluding any taxes paid on the income from such sales), to the extent ProNAi or its Affiliates are not otherwise entitled to a credit or a refund for such taxes, duties or payments made;

v. [*]; and

vi. [*].

Each of the deductions set out above shall be determined on an accrual basis in accordance with U.S. GAAP.

For the purposes of determining Net Sales, Licensed Products shall be deemed to be sold when invoiced and a "sale" shall not include transfers, uses or dispositions of sample product for promotional, preclinical or clinical trial, regulatory or governmental purposes in all cases provided that a "for profit" price is not charged. For purposes of calculating Net Sales, sales between or among ProNAi and/or its Affiliates and any of their Sub-Licensees shall be excluded from the computation of Net Sales, but sales by ProNAi and/or its Affiliates and any of their Sub-Licensee to Third Parties shall be included in the computation of Net Sales.

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With respect to Licensed Products that are sold as Combination Products (as defined below), then the Net Sales attributable to such Combination Product shall be calculated by multiplying actual Net Sales of such Combination Product by the fraction [*] where: A is the gross invoice price in the applicable country of the Licensed Product that does not contain any other therapeutically active ingredient (i.e. where it is not comprised in a Combination Product), and B is the gross invoice price in such country of the other therapeutically active ingredients or components contained in such Combination Product.

If "A" or "B" cannot be determined by reference to non-Combination Product sales as described above, then Net Sales will be calculated as above, but the gross invoice price in the above equation [*].

As used in this definition of Net Sales, "**Combination Product**" means a Licensed Product that contains one or more additional active ingredients or components (whether co-formulated or co-packaged) that are neither the Licensed Compound (or any compound or component covered by one or more claims of the Licensed Patents) nor generic or other non-proprietary compositions of matter. Pharmaceutical dosage form vehicles, adjuvants and excipients shall be deemed not to be "active ingredients."

With respect to any matter upon which this definition requires the Parties to reach mutual agreement, then in the absence of such mutual agreement, either Party may refer that disagreement to an expert for determination in accordance with clause 28.1.

"Non-Compound Intellectual Property" means any Licensed Intellectual Property other than Compound Intellectual Property and including any CHK1 Clinical SOPs.

"Non-Compound Materials" means Materials used in the CHK1 programme at the Effective Date which are not CHK1 Inhibitors.

"Non-Exclusive Licensed Intellectual Property" shall have the meaning given in Clause 3.1.1.

"Non-Performing Party" shall have the meaning given in Clause 16.1.

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"Oncology Indication" means an Indication in the range C00 – D48 (e.g. "C50 Malignant neoplasm of Breast", "C92 Myeloid leukaemia").

"Orphan Drug Designation" means designation as an orphan drug or equivalent under relevant national or other applicable regulations and/or legislation in any part of the world, including under the US Orphan Drug Act of 1983 or Orphan Drug Regulation 141/2000 in the European Union

"Other Indication" has the meaning given in Clause 3.4.

"Other Indication Notice" has the meaning given in Clause 3.4.

"Parties" means CPF and ProNAi and "**Party**" shall mean any of them.

"Patent Costs" means any external out of pocket costs and expenses incurred in filing, prosecuting, maintaining, defending and enforcing the Licensed Patents, including official filing, prosecution, maintenance and renewal fees, Patent attorney, translation, legal and other professional fees and expenses, and including costs and expenses associated with any quasi-litigious action such as an opposition or interference action.

"Patents" means any Patent applications, Patents, author certificates, inventor certificates, utility models, and all foreign counterparts of them and includes all divisionals, renewals, continuations, continuations-in-part, extensions, reissues, substitutions, confirmations, Registrations, revalidations and additions of or to them, as well as any Supplementary Protection Certificate, or any like form of protection.

"Person" shall mean an individual, corporation, partnership, limited liability company, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.

"Phase I Development Contribution" means [*].

"Phase I Trial" means a clinical trial in which a Licensed Product is administered to human subjects at multiple dose levels with the primary purpose of determining safety, metabolism, and pharmacokinetic and pharmacodynamic properties of the Licensed Product, and

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consistent with 21 CFR § 312.21(a) or its equivalent in different jurisdictions and any microdosing clinical trial conducted pursuant to the FDA's 2006 Guidance on Exploratory Investigational New Drugs or any equivalent arrangements.

"**Phase I Trial Costs**" means the [*] incurred by or on behalf of CPF in conducting the Phase I Clinical Trials of CCT245737 up to the Effective Date, and (b) any [*] incurred by or on behalf of CPF in conducting the Phase I Clinical Trial of CCT245737 following the Effective Date and prior to the transfer to ProNAi of the Product CTAs. For clarity, CPF's [*] costs of conducting the foregoing Phase I Clinical Trials may include [*] as [*] cost.

"Phase II Trial" means a randomized human clinical trial in any country that is intended to initially evaluate the effectiveness of a Licensed Product for a particular indication or indications in patients with the disease or indication under study [*]. For the avoidance of doubt, [*] shall not be a Phase II Clinical Trial.

"Phase III Trial" means a human clinical trial in any country, the results of which could be used to establish safety and efficacy of a Product as a basis for an NDA [*]. For the avoidance of doubt, [*] shall not prospectively be a Phase III Clinical Trial, unless [*].

"Price Approval" means, in those countries in the Territory where a Competent Authority may approve or determine pricing and/or pricing reimbursement for pharmaceutical products, such approval or determination.

"Product CTAs" means the CTAs for each of the two (2) Phase I Clinical Trials of CCT245737 being conducted by or on behalf of CPF as of the Effective Date.

"Product CTA Payment" shall have the meaning given in Clause 5.4.

"Product CTA Transfer Date" means the date that ProNAi is recognized as the CTA sponsor according to all of the MHRA, the HRA/REC, and the [*] active clinical trial sites, Royal Marsden, [*]. For the avoidance of doubt, this shall be the date on which ProNAi's sponsor contracts become effective after [*] such sites have approved the sponsor transition.

"Progress Report" means a summary written report produced by ProNAi in respect of: (i) the progress of development of Licensed Products in relation to the then-current Clinical Development Plan; (ii) if relevant, the progress of any applications for Registration and

(where relevant) Price Approvals for Licensed Products, and (iii) the progress of and plans for marketing and sale of Licensed Products. ProNAi agrees that each Progress Report shall include information that is reasonably sufficient for CPF to be able to ascertain ProNAi's progress with respect to the Key Activities, in order for CPF to fulfil its reporting obligations to CRT/ICR under the Upstream Licence Agreement. ProNAi shall provide Progress Reports at the frequency set forth in Clause 4.5.

"ProNAi Indemnified Parties" shall have the meaning given in Clause 10.2.

"Quarter" means any of the three-monthly periods commencing on the first day of any of the months of January, April, July, and October in any year and "**Quarterly"** has a corresponding meaning.

"Receiving Party" shall have the meaning given in Clause 13.1.

"Registration" or **"Registrational"** means any and all permits, licenses, clearances, authorisations, registrations or regulatory approvals (including NDAs) required and/or granted by any Competent Authority as a prerequisite to the development, manufacturing, packaging, marketing and selling of any Licensed Product prior to commercial sale of the relevant Licensed Product in the Field, including any necessary variations thereto, but excluding any Price Approvals.

"Representatives" shall have the meaning given in Clause 13.1.

"Revenue Information" shall have the meaning given in Clause 13.4.2

"Sareum" means Sareum Limited, a company registered in England under number 04863659 with registered office at Unit 2a Langford Arch London Road, Pampisford, Cambridge, Cambridgeshire, CB22 3FX.

"Signature Fee" means the non-refundable sum of seven million dollars (USD $7,000,000).

"Sub-Licensee" means a person to whom a sub-licence is granted in accordance with Clause 3.4 in respect of the whole or any part of the rights granted under this Agreement.

"Sub-Licence Provisions" means those provisions required to be included in a sub-licence pursuant to Clause 3.5, as further set out in Schedule 7.

"Substituted Sublicense" shall have the meaning given in Clause 14.3.

"Supplementary Protection Certificate" means a right based on a Patent pursuant to which the holder of the right is entitled to exclude Third Parties from using, making, having made, selling or otherwise disposing or offering to dispose of, importing or keeping the product to which the right relates, such as supplementary protection certificates in Europe, and any similar right anywhere in the world.

"Target Patent Country" means any one of the countries listed in Schedule 8.

"Term" means the term of this Agreement determined in accordance with Clause 14.1.

"Territory" means worldwide.

"Third Party" means a person other than a Party, their respective Affiliates or a Sub-Licensee.

"Third Party Service Provider" means CRUK or a Third Party who provides research, development and/or manufacturing services to ProNAi in connection with Licensed Products, including contract research organisations, universities and hospitals. However, a Tobacco Party may not act as a Third Party Service Provider.

"Tobacco Party" means: (i) any person who develops, sells or manufactures tobacco products; and/ or (ii) any person which makes the majority of its profits from the importation, marketing, sale or disposal of tobacco products. Furthermore, Tobacco Party shall include any person that is Controlled by or under common Control with any of the persons referred to in (i) and/or (ii).

"Transfer Deadline" shall have the meaning given in Clause 5.4.

"UK Pricing Authority" means any supra-national, national or regional government department, authority, agency or entity (including a non-departmental public body or similar entity) with responsibility for evaluating the cost effectiveness of medicinal products in the United Kingdom (or one or more constituent countries thereof) or otherwise determining whether the NHS (or constituent parts thereof) should purchase medicinal products.

"Upstream Licence Agreement" has the meaning given in Recital C.

"Valid Claim" means either:

i. a claim of an issued and unexpired Licensed Patent (which include any Patent term extension or Supplementary Protection Certificate) in the relevant country in the Territory which covers the Licensed Product and that: (i) has not been revoked or held unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal; or (ii) has not been abandoned, disclaimed, or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise; or

ii. a claim of a pending Patent application, which claim has been filed in good faith, and such application has been pending for less than [*] years from the earliest priority date, and has not been abandoned or finally disallowed without the possibility of appeal or re-filing of the application.

"Year" means a calendar year.

1.2 In this Agreement:

1.2.1 unless the context requires otherwise, all references to a particular Clause, paragraph or Schedule shall be references to that clause, paragraph or schedule, in or to this Agreement;

1.2.2 the table of contents and headings are inserted for convenience only and shall be ignored in construing this Agreement;

1.2.3 unless the contrary intention appears, words importing the masculine gender shall include the feminine and vice versa and words in the singular include the plural and vice versa;

1.2.4 unless the contrary intention appears, words denoting persons shall include

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any individual, partnership, company, corporation, joint venture, trust association, organisation or other entity, in each case whether or not having separate legal personality; and

1.2.5 references to the words "include" or "including" shall be construed without limitation to the generality of the preceding words.

2. [RESERVED]

3. LICENCE

3.1 Subject to the provisions of this Agreement, CPF hereby grants to ProNAi and its Affiliates:

3.1.1 an exclusive, royalty-bearing, worldwide licence under the Licensed Intellectual Property, with the right to sublicence in accordance with the remainder of this Article 3, to research, develop, use, keep, make, have made, import, sell, offer for sale and otherwise dispose of Licensed Products in the Field in the Territory for the Term, provided that ProNAi shall remain fully liable for the performance of its Affiliates and the compliance of any Affiliate exercising rights under the foregoing licence grant or performing activities under this Agreement as if they were the acts of ProNAi itself. Notwithstanding the foregoing exclusive licence grant, ProNAi acknowledges and agrees that with respect to any Licensed Intellectual Property that is not owned by nor exclusively licensed to CPF (including Non-Compound Intellectual Property, any Intellectual Property that CPF Controls pursuant to the MTAs and Biomarkers other than Exclusive Biomarkers) (the "**Non-Exclusive Licensed Intellectual Property**"), CPF has only non-exclusive rights in such Non-Exclusive Licensed Intellectual Property, and therefore the foregoing licence grant is exclusive only with respect to CPF's rights, and not with respect to any rights of any Third Party (including CPF's licensors), in such Non-Exclusive Licensed Intellectual Property; and

3.1.2 a non-exclusive, worldwide licence under any Patents or Know-How that are not included in the Licensed Intellectual Property and are otherwise Controlled by CPF or its Affiliates after the Effective Date (including, for clarity, any Patents and Know-How acquired or licensed by CPF from any Third Party after the Effective Date) that are necessary for ProNAi to practice the Licensed Patents, or the Licensed Know-How in connection with the

development and commercialization of Licensed Products in accordance with this Agreement (the "**Additional CPF Intellectual Property**"), in each case solely to the extent such Additional CPF Intellectual Property is Controlled by CPF, and solely to the extent that either (a) CPF does not owe a payment obligation under such Additional CPF Intellectual Property to any Third Party for the grant of such sublicence to ProNAi, or (b) if CPF owes a payment obligation under such Additional CPF Intellectual Property to a Third Party for the grant of such sublicence to ProNAi, that ProNAi has agreed in writing to make such payments to such Third Party, provided that nothing in this Clause 3.1.2 shall be deemed to constitute any obligation for CPF to disclose any Know-How or other Confidential Information to ProNAi that is not included within the Licensed Know-How. If CPF owes a payment obligation under such Additional CPF Intellectual Property to a Third Party for the grant of such sublicence to ProNAi, then CPF shall promptly notify ProNAi in writing after execution of the agreement with the Third Party for the applicable Additional CPF Intellectual Property and provide to ProNAi the applicable details of the payments owing to such Third Party. If ProNAi does not agree in writing to make the applicable payments to such Third Party, then such Additional CPF Intellectual Property shall not be included within the scope of the foregoing licence grant.

3.2 No licence to use any Intellectual Property is granted to ProNAi, or any Sub-Licensee or implied except the rights expressly granted in this Agreement.

3.3 CPF hereby reserves from the licence under Clause 3.1 a non-exclusive, worldwide, fully paid-up, perpetual and irrevocable right in and to Compound Intellectual Property and Exclusive Biomarkers (including use by scientists funded and employed by ICR and by scientists funded and employed by the CRUK) for ICR and CRUK to:

3.3.1 use Compound Intellectual Property and Exclusive Biomarkers for the purpose of non-commercial scientific research carried out by or for or under their respective direction in accordance with their respective charitable and academic status, whether alone or in collaboration with others and whether sponsored or funded, in whole or in part, by any person including a commercial entity provided that the intellectual property generated by any such commercially sponsored research shall not be owned by, or licensed to, a commercial Third Party on terms permitting such commercial Third Party to compete with ProNAi or any Sub-

Licensee in developing Compound Intellectual Property. For the avoidance of doubt, in relation to any Exclusive Biomarkers: (a) CRT, CRUK and ICR (including use by scientists funded and employed by ICR and CRUK) shall be entitled to use such Biomarkers for the purpose of scientific research carried out in accordance with their respective charitable and academic status, whether alone or in collaboration with others and whether sponsored or funded, in whole or in part, by any person including a commercial entity (and including any clinical research focused on any CHK1 Inhibitor developed by a Third Party) but shall (unless in accordance with (b) below) only make available to any Third Party any Biomarkers which have been demonstrated not to be Exclusive Biomarkers; (b) CRT, CRUK and ICR shall be entitled to make available such Biomarkers to any Third Party for the purpose of an evaluation only and in making such Biomarkers available, neither CRT, CRUK nor ICR shall disclose any Confidential Information of ProNAi available to such Third Party (for the avoidance of doubt, CRT and/or ICR and/or CRUK shall be permitted to disclose to such Third Party any Know How included within Non-Compound Intellectual Property and Know How concerning Biomarkers other than Exclusive Biomarkers);

3.3.2 make publications in relation to the Licensed Intellectual Property and any results of research using the same to the extent that it is within CRT's or ICR's or CRUK's control in accordance with Clause 27.4; provided that to the extent that CPF has such rights under the Upstream Licence Agreement, (a) CPF shall use reasonable efforts to ensure that reasonably in advance of any such publication the proposed manuscript will be provided to ProNAi for review and removal of any ProNAi Confidential Information (other than the Licensed Confidential Information) and (b) upon request by ProNAi, and to the extent within CPF's control under the Upstream Licence Agreement, CPF will delay any publication if necessary to file patent applications on patentable subject matter;

3.3.3 transfer the Licensed Materials and samples of Materials which are the subject of the Licensed Patents to academic or other not-for-profit Third Parties solely for the purpose of non-commercial research, provided that to the extent within CPF's control under the Upstream Licence Agreement, CPF shall use

reasonable efforts to ensure that such transfer occurs pursuant to a written agreement that provides for the recipient to grant to ICR and or CRUK, with the right to grant sublicenses to CPF (and the right to grant sub-sublicenses to ProNAi) a licence under any Intellectual Property that is generated by such recipient through the use of the Licensed Materials or such Materials that are the subject of the Licensed Patents; and

3.3.4 make available and grant licences to, the Compound Intellectual Property and Exclusive Biomarkers solely to the extent necessary to exercise its rights pursuant to Clauses 3.3.1 to 3.3.2, but not otherwise.

3.4 If ProNAi reasonably believes that pursuing an Oncology Indication is likely to result in a product which would offer no substantial benefit to the patient population over existing drugs, or drugs in development, for the Oncology Indications for which the Licensed Product would be most suitable, or if ProNAi wishes to develop and commercialise (or grant rights to a Third Party to develop or commercialise) a Licensed Product in an Indication other than an Oncology Indication (an "**Other Indication**"), then in such circumstances ProNAi shall provide written notice to CPF setting out its reasons, with supporting evidence, for such belief ("**Other Indication Notice**"), provided that (a) subject to providing an Other Indication Notice to CPF, ProNAi shall not need to obtain the consent of CPF (or CRT or CRUK) to pursue (or to grant rights to any Sub-Licensee to pursue) development and commercialization of a Licensed Product in an Other Indication concurrently with development and commercialization of Licensed Products in an Oncology Indication, provided that ProNAi complies with its obligations under this Agreement, including pursuant to Clauses 4.4 and 4.5, in an Oncology Indication.

If ProNAi (or its Sub-licensee, where such Sub-licensee is the party developing and commercializing Licensed Products in an Oncology Indication) is providing an Other Indication Notice to CPF where ProNAi (or any Sub-Licensee) is proposing to cease or scale back development and commercialization in all Oncology Indications (such that ProNAi would no longer meet its obligations under Clauses 4.4 and 4.5 in any Oncology Indication), but ProNAi (or such Sub-Licensee) intends to progress (or continue to progress) development and commercialization in an Other Indication, then [*] ProNAi shall [*] for an Oncology Indication. Specifically, ProNAi shall [*] with the purpose of

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either (i) [*] in Oncology Indications, or (ii) [*] (with respect to the [*]) and allow [*] (or any [*]) to [*] Oncology Indications, provided that (a) [*] following and as a result of the [*] shall not be [*] and shall not be [*] Oncology Indication under this Agreement, and (b) [*] and (ii) [*] or (iii) [*] in an Oncology Indication[*] shall be amended such that [*] shall apply in each case thereafter with respect to [*]. If, at [*] negotiation period, [*] believes there is [*] (which may involve [*]) to [*]. Following [*], the parties will [*]. If such [*], [*] will [*], whether to [*].

3.5 ProNAi shall be entitled to grant sub-licences (through multiple tiers) in respect of the rights granted under this Agreement, provided that with respect to any sub-licence granted to an entity (including any sub-sub-licence):

3.5.1 any sub-licence granted by ProNAi shall be expressed to terminate automatically on the termination of this Agreement for any reason. On such termination and provided the termination of this Agreement was not caused by a breach of the obligations under the relevant sub-licence CPF shall immediately grant to the affected Sub-Licensee a sub-licence on materially the same terms to that contained in the terminated sub-licence, save that this shall not result in CPF taking on any more onerous obligations or assuming any liability other than it is under pursuant to this Agreement. CPF shall continue to pay to ProNAi such sums as it would have received under the terminated sub-licence less the amount which ProNAi would have had to pay CPF pursuant to this Agreement and less any Patent Costs or other costs which would have been borne by ProNAi under such sublicence agreement, but for the termination of this Agreement, provided that if such Patent Costs or other costs exceed the amounts payable to ProNAi after such termination, CPF, and not ProNAi, shall be liable for any such excess costs. For the avoidance of doubt, expiry of this Agreement consequent upon the expiry of the Term of this Agreement shall not result in the automatic termination of any sub-licence;

3.5.2 ProNAi shall ensure that there are included in the terms of any sub-licence substantially equivalent obligations and undertakings on the part of the Sub-Licensee to those applying to ProNAi in this Agreement (except this Clause 3.5 3.5.1). In particular, ProNAi shall ensure that any sub-licence has provisions which secure CPF, CRT's and ICR's (as the case may be) rights pursuant to Clause 8.8 and

8.9 (Patent enforcement), Clause 10 (indemnity for CPF Indemnified Parties), Clause 13 (Confidentiality) and Clause 15.1.8 (CPF's rights on termination). ProNAi shall additionally ensure that there are included in the terms of any sub-licence substantially equivalent obligations and undertakings to those set out in the Sub-Licence Provisions, and shall use Commercially Reasonable Efforts to ensure that all Sub-Licensees duly comply with the same.

3.5.3 within thirty (30) Business Days of the grant of any sub-licence, ProNAi shall provide CPF with a true copy of such sub-licence at ProNAi's expense; provided that ProNAi may redact any terms that are unnecessary for CPF to determine compliance with this Agreement as a whole, and provided further that such copy shall include the name of the sub-licensee, unredacted;

3.5.4 no sub-licence shall knowingly be granted to a Tobacco Party, provided that if, following the grant of such a sub-licence, either Party becomes aware that such Sub-licensee is a Tobacco Party, then ProNAi shall promptly notify CPF, and shall forthwith terminate such sub-license;

3.5.5 the sub-licence shall be entered into on an arms-length basis;

3.5.6 Any act or omission of any Sub-Licensee which, if it were the act or omission of ProNAi would be a breach of any of the provisions of this Agreement, will be deemed to be a breach of this Agreement by ProNAi who will be liable to CPF (as the case may be) accordingly.

3.6 The foregoing obligations shall not apply in relation to contracts ProNAi enters into with Third Party Service Providers, provided that: (a) such contracts relate to the provision of research, development and/or manufacturing services to ProNAi in connection with the Licensed Products; and (b) no rights are granted to the Third Party to: (i) research, develop or manufacture its own products; or (ii) sell Licensed Products. ProNAi will ensure that an appropriate written agreement is put in place with each Third Party Service Provider.

3.7 The grant of any sub-licence shall be without prejudice to ProNAi's obligations under this Agreement.

4. PERFORMANCE

4.1 The Parties have agreed upon a preliminary draft of the Clinical Development Plan attached at Schedule 9. Following the Effective Date, and based on the additional information available to ProNAi as a result of the transfer of the Licensed Materials and the Product CTAs, and access to the Licensed Intellectual Property, ProNAi shall prepare a final version of the initial Clinical Development Plan, which shall be annexed to this Agreement as an updated Schedule 9, and a copy of which shall be provided to CPF by the later of (a) six (6) months following the Effective Date, and (b) ninety (90) days following the completed transfer of the Product CTAs to ProNAi. The Clinical Development Plan shall be updated by ProNAi as necessary during the Term, and ProNAi shall report on any material updates in its Progress Reports provided to CPF pursuant to Clause 4.5.

4.2 (a) Promptly following the Effective Date, CPF shall provide, and [*], CCT245737 (raw materials, intermediates, and finished forms, including all clinical trial material) in inventory, and (b) promptly following ProNAi's reasonable request, CPF shall provide, and [*] any other available CHK1 Inhibitor in its or CRUK's possession that are included in the Licensed Materials, in each case for use in the development of Licensed Products at no cost to ProNAi. CPF shall provide such technical assistance to ProNAi as ProNAi reasonably requests for the transfer of technology subject to the licenses granted hereunder (including transferring the Licensed Materials and methods of manufacturing of the Licensed Materials), provided that (a) such technical assistance shall be provided for a maximum of [*] at CPF's expense, and thereafter at ProNAi's expense, and (b) ProNAi shall be responsible for reimbursing any out-of-pocket costs incurred by CPF in performing such transfer and/or providing any such technical assistance, including any amounts paid to [*] any Third Party by CPF in effecting the foregoing transfer or technical assistance, provided that prior to incurring any such out-of-pocket costs, CPF shall provide ProNAi with a good faith estimate of the nature and amount of such costs, and shall obtain ProNAi's prior approval before incurring such costs.

4.3 Within [*] days following the Effective Date, CPF shall use Commercially Reasonable Efforts to transfer to ProNAi the Product CTAs, and all supporting materials and documentation associated therewith, provided that if the transfer of the Product CTAs

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has not been completed [*] days following the Effective Date, the Parties will promptly meet to discuss in good faith the steps to be taken to procure the transfer of the Product CTAs as soon as practicable, and to facilitate the ongoing conduct of the Phase I Clinical Trials until such transfer is completed. In such circumstances, CPF will provide such assistance as ProNAi reasonably requests in procuring such transfer and continuing such Phase I Clinical Trials, subject to Clause 5.3. Attached hereto as Schedule 4 is a list of the activities to be undertaken by the Parties to properly effect the transfer of the Product CTAs, and the associated timeline for such activities, and each Party shall use Commercially Reasonable Efforts to perform its respective activities under Schedule 4. ProNAi hereby grants to CPF a limited, non-exclusive, royalty-free sub-licence under the rights granted to ProNAi pursuant to Clause 3.1, to the extent necessary for CPF to effect the transfer of the Product CTAs in accordance with this Clause 4.3, and to perform any activities in relation to the Phase I Clinical Trials that are the subject of such Product CTAs. The foregoing sub-licence shall include the right for CPF to grant further sub-licenses to Third Parties, including CRUK to carry out activities in relation to the transfer of the Product CTAs, including the ongoing conduct of the Phase I Clinical Trials, solely to the extent that such Third Parties are performing activities for or on behalf of CPF. Without limiting the foregoing, during the Term, CPF shall provide to ProNAi any Know-How created by or on behalf of CPF or any Affiliate after the Effective Date as a result of CPF's conduct of activities in relation to the Phase I Clinical Trials of CCT245737 and any Know-How that is generated under, and provided to CPF pursuant to, the MTAs, to the extent directly related to CHK1 Inhibitors.

4.4 ProNAi will use Commercially Reasonable Efforts to carry out the Clinical Development Plan, as amended from time to time, and use Commercially Reasonable Efforts to develop and commercialise in each of the Major Markets at least one (1) Licensed Product with an application in an Oncology Indication, save that nothing in this Clause 4.4 shall prevent ProNAi or its Affiliate from developing a Product outside of an Oncology Indication (subject to Clause 3.4), or granting sub-licences to Sub-Licensees authorising them to use the rights sublicensed to pursue other indications, subject to the requirements set forth in paragraph 1 of Schedule 7. ProNAi shall pass any Other Indication Notices delivered by any such sub-licensee to CPF for CPF's information. ProNAi will ensure that (a) each Licensed Product receiving a European wide Registration or a United Kingdom-specific

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Registration for launch is made available for purchase throughout the United Kingdom within [*] months of such Registration, and (b) any Licensed Product that has received a European wide Registration or a United Kingdom-specific Registration in respect of an Oncology Indication is made available following First Commercial Sale throughout the United Kingdom [*]. For clarity, the requirement in the foregoing (a) and (b) shall apply with respect to a European-wide Registration, only if such European-wide Registration also applies to permit commercialization in the United Kingdom upon substantially similar terms, without the requirement for further material regulatory activities or filings in order to commence such commercialization in the United Kingdom.

4.5 ProNAi shall:

4.5.1 Until the filing of an IND for the first Licensed Product, provide CPF with a Progress Report twice every Year, within sixty (60) days of the December and June Quarter ends;

4.5.2 Following the filing of an IND, and until First Commercial Sale of the first Licensed Product, provide CPF with a Progress Report once every Year, by January 31st;

4.5.3 promptly respond to any reasonable queries that CPF may have following receipt of a Progress Report or updated Clinical Development Plan;

4.5.4 at CPF's request, meet once per Year with CPF (either in person or by teleconference if a face-to-face meeting is not practical) to discuss the content of a particular Progress Report or updated Clinical Development Plan, and to respond to CPF's reasonable inquiries regarding any significant differences between the Clinical Development Plan and those activities actually undertaken or achieved;

4.6 If at any time during the course of the development or commercialisation of a Licensed Product, ProNAi fails to meet one or more of its obligations under Clauses 4.4 and 4.5 in relation to such Licensed Product for a period of [*] months or more, save where due to the acts or omissions of CPF, then CPF shall have the right to give written notice to ProNAi requesting detailed written justification for such failure and ProNAi shall provide

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such detailed written justification to CPF within thirty (30) Business Days of the date of CPF's request. Where remedy is possible ProNAi shall use its Commercially Reasonable Efforts to take substantive steps to remedy such failure within sixty (60) Business Days of the date of CPF's request. If ProNAi fails to provide such justification to CPF within thirty (30) days of the date of CPF's request and/or use its Commercially Reasonable Efforts to take substantive steps to remedy such failure within sixty (60) Business Days of the date of CPF's request, then, on notice by CPF to ProNAi, this Agreement will terminate in respect of the relevant Licensed Product. Any dispute between the Parties as to whether a diligence failure has arisen or whether ProNAi has used its Commercially Reasonable Efforts to take substantive steps to remedy a diligence failure shall be resolved by the Expert.

4.7 CPF shall pay in full all amounts required to be paid by CPF, and perform in full all obligations required to be performed by CPF, under all CPF In-Licenses. CPF promptly shall provide ProNAi with copies of all notices and other deliveries received under the CPF In-Licenses. Without the prior express written consent of ProNAi, CPF shall not (and shall take no action or make no omission to) modify or waive any provision of any CPF In-Licence that could impair the value of the licenses to ProNAi herein, or to terminate or have terminated any CPF In-License.

4.8 Promptly following the Effective Date, CPF shall provide ProNAi with a copy of all information available to CPF as at the Effective Date relating to the Licensed Intellectual Property and Licensed Products including without limitation: (i) relevant regulatory submissions; (ii) relevant communications with Competent Authorities (including the minutes of any meetings); (iii) relevant trial master files, including case report forms; (iv) listings and tables of results from the relevant clinical trials; (v) treatment-related serious adverse event reports from the relevant clinical trials; (vi) access to any retained samples of materials used in clinical trials; and (vii) CPF will use its reasonable efforts to provide ProNAi access, where permissible, to Third Parties involved in the relevant clinical trials.

5. CONSIDERATION

5.1 On the Effective Date, CPF shall provide to ProNAi an invoice for the Signature Fee, and ProNAi shall pay the Signature Fee to CPF within fifteen (15) Business Days of the receipt of invoice.

5.2 CPF has prepared a statement of the Phase I Trial Costs incurred as of the Effective Date, which is attached to this Agreement as in Schedule 11. Simultaneous with the execution of this Agreement, CPF shall provide ProNAi with all matching invoices evidencing the Phase I Trial Costs set forth in Schedule 11.

5.3 CPF shall pay to ProNAi within fifteen (15) Business Days following the Effective Date, the Phase I Development Contribution, less the Phase I Trial Costs incurred as of the Effective Date (as set forth in Schedule 11). CPF shall have no obligation to incur Phase I Trial Costs in excess of [*]. If CPF incurs Phase I Trial Costs after the Effective Date CPF shall provide ProNAi with an invoice from CRUK for such Phase I Trial Costs, and ProNAi shall pay such amount to CPF within thirty (30) days following the receipt of such invoice. Such process shall continue until up to sixty (60) days after the Product CTA Transfer Date, at which point only invoices that have been received by ProNAi shall be deemed to be included in the final statement of CPF Phase I Trial Costs.

5.4 Following the successful completion of the Product CTA Transfer Date ProNAi shall pay to CPF the following amount (as applicable based on the Product CTA Transfer Date) (the "**Product CTA Payment**"), to be made as specified in Clause 6.2.2: (a) [*] two million dollars (USD $2,000,000)[*], then [*].

5.5 ProNAi shall pay the payments ("**Milestone Payment**") to CPF one-time upon the first occurrence of each of the events ("**Milestone Event**") in relation to the first Licensed Product to achieve the applicable Milestone Event as set out in Schedule 6. For clarity, if a second or subsequent Licensed Product obtains Registration for a different Indication than the Indication for which the first Licensed Product (or such second Licensed Product, as applicable) has achieved Registration, the Milestone Payments due for Registration of a Licensed Product in a second and/or third Indication will be payable upon the achievement of Registration in each applicable country for the first (different) Indication for such second and/or subsequent Licensed Product, provided that each of the Milestone Payments for the first, second and third Indications for Licensed Product shall be paid only once, irrespective of how many Licensed Products achieve each such Milestone Event.

5.6 Subject to any more favourable arrangements concluded pursuant to Clause 5, ProNAi shall pay to CPF the royalties on Net Sales as set out in Schedule 6 on a Licensed Product by Licensed Product, and country by country basis until the later of:

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a) the date when the Licensed Product is no longer within the scope of a Valid Claim of a Licensed Patent in the country of sale or manufacture; and

b) the expiry of any Extended Exclusivity Period in the relevant country,

provided that on a country-by-country and Licensed Product-by-Licensed Product basis, if a Generic Product for a Licensed Product is being sold in such country, the royalties payable by ProNAi in respect of that country and that Licensed Product shall be reduced by the amounts set forth in the table below, from the first full Quarter following the launch of such Generic Product, [*] sold in such country.

Measured impact on Net Sales in the Relevant Country in the Applicable Calendar Quarter	**Royalty Rate applicable to Net Sales in such Country in the Applicable Calendar Quarter**
Net Sales reduced by [*]	[*]
Net Sales reduced by [*]	[*]
Net Sales reduced by [*]	[*]

In this table, [*] means, with respect to the [*] in such country [*] in such country. [*] in such country, then the [*] shall be determined [*], whether [*] (in which case it shall be [*]) or [*] (in which case the [*]).

5.7 If ProNAi, its Affiliate or Sub-Licensee are required, in any country in any Quarter, to pay [*] to a Third Party in consideration for the grant of rights under [*] Controlled by such Third Party that are [*] to make, use, sell, offer for sale or import a Licensed Product during such Quarter, then ProNAi shall have the right to credit the [*] paid to such Third Party, up to [*] against the royalties owing under Clause 5.6 with respect to sales of such Licensed Product during such Quarter. In no event shall the royalty rate applicable under Clause 5.6 on any Licensed Product in any Quarter be reduced due to credits for [*] under this Clause 5.7 by [*]. Notwithstanding the foregoing, the royalty offset set forth in this Clause 5.7 shall not apply to any [*] payable by ProNAi for any grant of rights under [*] in

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order to make, use, sell, offer for sale or import (a) [*], where such [*] are not [*] the manufacture, use, sale, offer for sale or import of the Licensed Compound (or any compound or component covered by one or more claims of the Licensed Patents) [*], or (b) the [*].

5.8 In the event that ProNAi negotiates a definition of sales (including 'net sales') and/or a royalty term in respect of which royalties are payable and/or a reduction for generic competition in any sub-licence, which results in greater payments being received by ProNAi than would be received if the definition of Net Sales as defined in this Agreement and/or the royalty term and/or a reduction for generic competition as set out in Clause 5, had been used, the definition of Net Sales and/or Clause 5 shall be amended to match that in the sub-licence in respect of all royalties payable from sales under such sub-licence.

5.9 Within sixty (60) days after the end of each Quarter following the First Commercial Sale of Licensed Product, ProNAi shall send to CPF a written statement detailing in respect of that Quarter (including a nil report if appropriate):

a) any Milestone Event achieved by it or any Sub-Licensee and any Milestone Payment which became due to CPF;

b) the quantity of Licensed Product sold or otherwise disposed of by ProNAi or any Sub-Licensees in the Territory;

c) the Net Sales in respect of each such type of Licensed Product in each country of the Territory;

d) the aggregate Net Sales in respect of that Quarter for Licensed Product;

e) the aggregate deductions made in the calculation of Net Sales under each subcategory (i) through (vi) in the definition of Net Sales, by type of Licensed Product;

f) the calculation of the royalties, if any, that shall have accrued based upon such Net Sales;

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g) subject to Clause 6.3, any currency conversions, showing the rates used;

h) the amount of the royalties due to CPF in respect of that Quarter; and

i) the withholding taxes, if any, required by law to be deducted with respect to such sales

6. PAYMENT AND STATEMENT

6.1 All payments due to CPF under this Agreement shall be made in US dollars (USD $) in cleared funds to the following bank account:

Account name: [*]
Account number: [*]
Sort code: [*]
IBAN: [*]
BIC: [*]
SWIFT CODE: [*]
Address: [*]

or such other account as CPF may notify ProNAi from time to time.

6.2 ProNAi shall pay to CPF:

6.2.1 the Signature Fee on the date specified in Clause 5.1;

6.2.2 the Product CTA Payment under and subject to Clause 5.2 [*] after the Product CTA Transfer Date provided that CPF shall invoice ProNAi for the Product CTA Payment on the Product CTA Transfer Date;

6.2.3 each Milestone Payment due under Clause 5.5 within [*] of receipt of invoice from CPF after the Milestone Event occurring, provided that ProNAi shall notify CPF in writing of the occurrence of any Milestone Event within [*] of the same, upon which CPF shall invoice ProNAi for the applicable Milestone Payment;

6.2.4 any royalties due pursuant to Clause 5.6 Quarterly [*] following the end of each Quarter in which the relevant Net Sales are invoiced by ProNAi or a Sub-Licensee; and

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6.3 Where Licensed Products are sold in a currency other than United States Dollars (USD), the rate of exchange to be used for converting such other currency into USD shall be the average of the exchange rate (local currency per USD$1) published in the Wall Street Journal, Western Edition, under the heading "Currency Trading" on the first Business Day of each month in the Quarter.

6.4 All costs of transmission and currency conversion shall be borne by ProNAi.

6.5 Tax.

6.5.1 All payments to CPF under this Agreement are expressed to be exclusive of indirect taxes (such as value added tax, sales tax, consumption tax and other similar taxes ("**Indirect Taxes**")) howsoever arising. ProNAi shall pay all accurately applied Indirect Taxes to CPF in addition to those payments or, if earlier, on receipt of a tax invoice or invoices from CPF as applicable, all Indirect Taxes for which CPF is liable to account in relation to any supply made or deemed to be made for value added tax purposes pursuant to this Agreement, such Indirect Taxes to be payable on the due date of the payment of the Payments to which such Indirect Taxes relate. The Parties shall issue invoices for all goods and services supplied under this Agreement consistent with Indirect Tax requirements. [*].

6.5.2 If ProNAi is required by law to make any such tax deduction or withholding, ProNAi shall be entitled to deduct and withhold from any amounts payable under this Agreement such taxes as are required to be deducted or withheld therefrom under any provision of Applicable Law. ProNAi shall: (i) deduct those taxes from such payment, (ii) timely remit the taxes to the proper taxing authority, and (iii) promptly give CPF proper evidence as to the deduction or withholding and payment over of the tax deducted or withheld; provided, however, that before making any such deduction or withholding, ProNAi shall give CPF notice of the intention to make such deduction or withholding (such notice, which shall include the authority, basis and method of calculation for the proposed deduction or withholding, shall be given at least a reasonable period of time before such deduction or withholding is required, in order for such other Party to obtain reduction of or relief from such deduction or withholding). ProNAi shall give reasonable assistance to CPF to claim refunds or

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exemption from such deductions or withholdings under any relevant agreement or treaty which is in effect to ensure that any amounts required to be withheld pursuant to this Clause 6.5.2 are reduced in amount to the fullest extent permitted by Applicable Laws. Any and all expenses incurred by ProNAi in providing such assistance shall be fully reimbursed by CPF. In addition, the Parties shall cooperate in accordance with applicable Laws to minimize withholding in connection with this Agreement; provided that subject to Clause 6.5.3, such cooperation shall not prohibit ProNAi from making changes to its business in due course.

6.5.3 Tax Gross-up. Notwithstanding the foregoing, if either Party (or its assignee pursuant to Clause 17.1.2) takes any action (including an assignment pursuant to Clause 17.1.2) and if as a result of such action, such Party (or its assignee pursuant to Clause 17.1.2) is required by applicable Law to withhold taxes, or if such action results in the imposition of Indirect Taxes that were not otherwise applicable, from or in respect of any amount payable under this Agreement, and such withholding taxes or Indirect Taxes exceed the amount of withholding taxes or Indirect Taxes that would have been applicable if such action had not occurred, then any such amount payable shall be increased to take into account such increased withholding taxes or Indirect Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts) and/or paying such Indirect Taxes, as the case may be, the other Party (or its assignee pursuant to Clause 17.1.2) receives an amount equal to the sum it would have received had no such increased withholding been made and no such Indirect Taxes had been imposed; provided, however, that the paying Party will have no obligation to pay any additional amount under the immediately preceding clause to the extent that such increased withholding tax or such Indirect Taxes would not have been imposed but for (A) the assignment by the other Party pursuant to Clause 17.1.2 of its rights under this Agreement or any redomiciliation of the other Party outside of the United States (in the case of ProNAi) or the United Kingdom (in the case of CPF), to the extent such assignment or redomiciliation occurs after the initial action by the paying Party described in the first sentence of this Clause 6.5.3 or (B) the failure by the other Party to comply with the requirements of Clause 6.5.2.

6.5.4 Tax Documentation. Each Party has provided a properly completed and duly executed IRS Form W-9 or other applicable Form to the other Party. Each Party and any other recipient of payments under this Agreement shall provide to the other Party, at the time or times reasonably requested by such other Party or as required by applicable Law, such properly completed and duly executed documentation (for example, IRS Forms W-8 or W-9) as will permit payments made under this Agreement to be made without, or at a reduced rate of, withholding for taxes.

6.6 Where the payee does not receive payment of any undisputed sums properly due and payable to it under this Agreement within the relevant period, interest shall accrue on the sum due and owing at the rate equivalent to an annual rate of two percent (2%) over the then current base rate of LIBOR, calculated on a daily basis, without prejudice to payee's right to receive payment within the relevant period, provided always the provisions of this Clause shall not apply to the extent and for the period that a Force Majeure event prevents payment.

7. ACCOUNTS

7.1 ProNAi shall:

7.1.1 keep and notwithstanding the expiry or termination of this Agreement, maintain and shall use its Commercially Reasonable Efforts to procure that each Sub-Licensee keeps and maintains, for at least [*] years, true and accurate accounts and records (including any underlying documents supporting such accounts and records) in sufficient detail to enable the amount of all sums payable under this Agreement (including determination of any permissible deductions set forth in subclauses (i) through (vi) of the definition of Net Sales) to be determined; and

7.1.2 during the Term and thereafter until the period of [*] years relevant to the accounts and records has expired, no more frequently than once a Year, at the reasonable request of CPF and at the expense of CPF from time to time, permit or procure permission for an independent certified public accounting firm of nationally recognized standing nominated by CPF, and reasonably acceptable to ProNAi, to inspect and audit those accounts and records and, to the extent that they relate to the calculation of those sums, to take copies of them.

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7.2 If, following any inspection pursuant to Clause 7.1.1, and in the absence of manifest error, CPF's nominated accountant certifies that the total payments in respect of the period audited fall short of the sums which were properly payable in respect of the period audited under this Agreement, CPF shall send a copy of the certificate to ProNAi and ProNAi shall (subject to Clause 7.4) within [*] of the date of receipt of the certificate pay the shortfall to CPF and, if the shortfall exceeds [*] of the sum properly payable during the period audited, ProNAi shall also reimburse to CPF the reasonable costs and expenses of CPF in making the inspection.

7.3 CPF shall cause its accounting firm to retain all financial information subject to review under this Clause 7 in strict confidence; provided, however, that ProNAi shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with ProNAi regarding such financial information. The accounting firm shall disclose to CPF only whether the reports are correct or not and the amount of any discrepancy. No other information shall be shared. CPF shall treat all such financial information as ProNAi's Confidential Information.

7.4 If within [*] of the date of receipt by ProNAi of any certificate produced pursuant to Clause 7.2, ProNAi notifies CPF in writing that it disputes the certificate, the dispute shall be [*].

8. INTELLECTUAL PROPERTY MANAGEMENT

8.1 All Patent Costs incurred after the Effective Date shall be met solely by ProNAi.

8.2 The ownership of the Licensed Intellectual Property shall at all times remain vested solely in CRT. CPF represents and warrants to ProNAi that as of the Effective Date it does not own or controls any Patent (other than the Licensed Patents) which cover equivalent subject matter (concerning CHK1) to the Licensed Patents.

8.3 Subject to Clauses 8.4, 8.5 and 8.6, ProNAi shall have the right to control the filing, prosecuting and maintaining the Licensed Patents in CRT's sole name and will use its Commercially Reasonable Efforts to maximise the duration and scope thereof in the Target Patent Countries.

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8.4 ProNAi shall keep CPF reasonably informed in advance of the filing and prosecution strategy for the Licensed Patents, and shall take into consideration all comments received from CPF in respect thereof. If ProNAi elects not to file a Patent application, in any Target Patent Country ProNAi shall promptly notify CPF of such decision and CPF shall have the right (but not the obligation) to file such an application. If CPF elects to exercise such right by notice in writing to ProNAi, CPF shall thereafter be solely responsible for the expense of filing, prosecuting and maintaining the corresponding Patent, which shall be excluded from the definition of Licensed Patents and the licence granted under Clause 3.1.

8.5 ProNAi shall keep CPF reasonably informed in writing as to the prosecution and/or maintenance status of the Licensed Patents and shall promptly provide CPF with a copy of all material submissions made to or material responses received from the relevant Patent offices and all correspondence to and responses received from the relevant Patent agent in relation to the Licensed Patents in each applicable country of the Territory. ProNAi shall use Commercially Reasonable Efforts to notify CPF at least three (3) months prior to any restriction of scope of any of the Licensed Patents.

8.6 If ProNAi elects not to prosecute and/or maintain any part of the Licensed Patents in any Target Patent Country, ProNAi shall notify CPF in writing and shall use Commercially Reasonable Efforts to ensure that such notice is given at least [*] prior to the expiration of any applicable time bars. During the aforementioned [*] notice period, ProNAi shall continue to prosecute and maintain the Licensed Patents in question. On the expiry of such notice period:

8.6.1 the licence granted pursuant to Clause 3.1 shall terminate in respect of the Licensed Patents identified in such notice; and

8.6.2 ProNAi shall, at CPF's request, promptly transfer to CPF any and all documents and information in ProNAi's control relating to such Licensed Patents; and

8.6.3 CPF shall have the right, but not the obligation, to prosecute (or abandon) such Licensed Patents at its sole discretion and to grant rights thereunder to any person without further reference to ProNAi.

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8.7 Each Party will promptly notify the other Parties in writing as soon as it becomes aware of any infringement or suspected infringement by a Third Party of any of the Licensed Patents or any unauthorised use of the Licensed Know How or the Licensed Materials in the Field (an "**Infringement Action**").

8.8 Provided ProNAi has a licence under this Agreement in relation to the relevant Licensed Patent and country (and where local law permits), within such country ProNAi may at its sole discretion:

8.8.1 at its own cost and subject to Clause 8.9, bring proceedings in its own name (or authorize a Sub-Licensee to bring proceedings in its own name) or, if required by law (including as required for standing), jointly with CPF (and CRT and/or ICR, if required for standing), for any Infringement Action; and

8.8.2 in any such proceedings settle any Infringement Action, provided it obtains the prior written consent of CPF, where any such settlement would result in a restriction to the scope of such Licensed Patent.

8.9 (a) Any damages, profits, and awards of whatever nature recovered by ProNAi or any Sub-Licensee for any Infringement Action shall be treated as Net Sales subject to a deduction for external legal expenses of ProNAi and such Sub-Licensee insofar as these are not recovered from a Third Party, provided always, where damages are also awarded to CPF to the extent that this would otherwise result in a double receipt by CPF of royalties ProNAi shall be entitled to deduct any such duplicated payment from any royalties payable to CPF. In any such proceedings, CPF shall, at ProNAi's cost, promptly provide ProNAi with all documents and assistance as ProNAi may reasonably require. ProNAi shall promptly provide CPF with notice of such proceedings and keep CPF regularly informed of progress and promptly provide CPF with such information as CPF may require including copies of all documents filed at court in the proceedings. If CPF (or CRT and/or ICR) is joined to proceedings pursuant to this Clause or otherwise, ProNAi shall indemnify and hold harmless the CPF Indemnified Parties and the inventors named in any Licensed Patents (the "**CPF Indemnitees**") from and against any and all claims, demands, losses, causes of action, damages and expenses (including without limitation, legal fees) arising from or in connection with such proceedings.

(b) If ProNAi does not exercise its right to bring proceedings pursuant to Clause 8.8 within [*] of written request to bring proceedings from CPF, then CPF shall be entitled, but not obliged to bring such proceedings at its own cost. If necessary, including to recover damages, subject to ProNAi's consent (such consent not to be unreasonably withheld or delayed it being agreed that the lack of indemnity protection for ProNAi would be reasonable grounds to refuse consent) CPF may require ProNAi to join in such proceedings. ProNAi shall have the right to join in any such proceedings commenced by CPF, subject to [*]. Any damages, profits, and awards of whatever nature recovered as a result of such a joint proceeding shall be [*] after deduction for external legal expenses of both Parties.

(c) In any proceedings in clauses (a) or (b), the Parties not bringing the proceedings ("**Inactive Parties**") shall promptly provide the Party bringing proceedings ("**Active Party**") with all documents and assistance as the Active Party may reasonably require and the Active Party shall promptly provide the Inactive Parties with notice of such proceedings.

8.10 The Parties shall, at the request of any of them and at the expense of the requesting Party but for no further consideration, enter into such confirmatory Patent licences relating to the Licensed Patents, substantially in the form set out in Schedule 10, as may be necessary or desirable in accordance with the relevant law and practice in each country in the Territory for Registration at the relevant Patent offices so that this Agreement need not be registered or recorded unless the Parties are required to do so by law. If there are any inconsistencies between the terms of any such confirmatory Patent licence and the provisions of this Agreement, this Agreement shall prevail.

8.11 With respect to each Licensed Product, ProNAi shall, at the time of receipt of the relevant Regulatory Approval, or such other time as appropriate, apply for a Supplementary Protection Certificate, Patent term extension and/or any other exclusivity in respect of such Licensed Product. Without limiting the foregoing, the selection of any patent to be subject to any patent term extension for any Licensed Product shall be made by ProNAi in its sole discretion. At ProNAi's reasonable request and sole cost, CPF will provide reasonable assistance to ProNAi in connection with any such applications.

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9. WARRANTY

9.1 Each Party acknowledges that, in entering into this Agreement, it does not do so in reliance on any warranty or other provision except as expressly provided in this Agreement, and all conditions, warranties, terms and undertakings implied by statute, common law or otherwise are excluded from this Agreement to the fullest extent permissible by law.

9.2 Each Party warrants to the others that it has the power and authority and the legal right to enter into this Agreement to which it is a Party and to perform its obligations hereunder and has taken all necessary action on its part required to authorise the execution and delivery of this Agreement to which it is a Party. This Agreement has been duly executed and delivered on behalf of such Party and in the case of CPF execution on its behalf by the General Partner constitutes a legal, valid and binding execution and is enforceable against it in accordance with its terms.

9.3 CPF hereby represents and warrants to ProNAi as at the Effective Date of this Agreement:

9.3.1 CPF is the sole owner or exclusive licensee of the Licensed Intellectual Property, and except with respect to rights granted to Third Parties under the MTAs, CPF has not granted to any Third Party any licence or other interest in the Licensed Intellectual Property.

9.3.2 [*].

9.3.3 Neither CPF nor its Affiliates are [*].

9.3.4 To CPF's knowledge, CPF has provided to ProNAi [*], provided that if either Party [*] such [*] shall be [*].

9.3.5 CPF has provided ProNAi with complete and correct copies of (i) the form of agreement on which each MTA is based, and for the final form of each executed MTA[*] and (ii) CPF In-Licences, and there have been [*] prior to the Effective

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Date. Except with respect to those MTAs expressly stated not to have been executed as of the Effective Date, the MTAs and CPF In-Licences are in full force and effect in accordance with their terms.

9.3.6 CPF is not in breach of any executed MTAs or CPF In-Licence and signing this Agreement does not put CPF in breach, default or cause events which would (with the giving of notice, the passage of time or both) give rise to a breach, default or other right to terminate or modify any executed MTAs or CPF In-Licence.

9.3.7 Except to the extent necessary for the conduct of the Phase I Clinical Trials for 737, CPF has not transferred or granted, and CPF shall not transfer or grant, to any Third Party any licence or other interest in the MTAs or CPF In-Licences.

9.4 Without limiting the scope of Clause 9.1, CPF does not give any warranty, representation or undertaking in relation to the Licensed Intellectual Property, including any warranty, representation or undertaking:

9.4.1 as to the efficacy, usefulness, completeness or accuracy of the Licensed Intellectual Property; or

9.4.2 that any of the Licensed Patents is or will be valid or that any of the applications within the Licensed Patents will proceed to grant; or

9.4.3 that the use of any Licensed Intellectual Property, including without limitation any invention claimed in a Licensed Patent, or the exercise of any rights granted under this Agreement will not infringe the Intellectual Property or other rights of any other person.

10. INDEMNITY

10.1 ProNAi shall indemnify, defend and hold harmless CPF Indemnified Parties from and against any and all third party claims, demands, losses, damages, costs and expenses (including, without limitation, legal fees) arising from or in connection with the exercise by ProNAi or a Sub-Licensee of the rights granted in Clause 3.1 or the actions of ProNAi, or a Sub-Licensee in relation to a Licensed Product.

10.2 CPF shall indemnify, defend and hold harmless ProNAi and its respective officers, employees and agents (the "**ProNAi Indemnified Parties**") from and against any and all third party claims, demands, losses, damages, costs and expenses (including, without limitation, legal fees) arising from or in connection with a breach of any representation, warranty or covenant of CPF under this Agreement.

10.3 Promptly after receipt by a Party seeking indemnification (the "**Indemnitee**") of any claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation to which the indemnity provided for in this Clause 10 may apply, the Indemnitee shall give written notice to the other Party (the "**Indemnitor**") of such fact and the Indemnitor shall have the option to assume the defence thereof by election in writing within thirty (30) days of receipt of the Indemnitee's notice. If the Indemnitor fails to make such election, the Indemnitee may assume such defence and the Indemnitor will be liable for the legal and other expenses consequently incurred in connection with such defence. The Parties will co-operate in good faith in the conduct of any defence, will provide such reasonable assistance as may be required to enable any claim to be defended properly and the Party with conduct of the action shall promptly provide to the other Party copies of all correspondence and documents and notice in writing of the substance of all oral communications relating to such action.

10.4 Should the Indemnitor assume conduct of the defence:

10.4.1 the Indemnitee may retain separate legal advisers, at its sole cost and expense; and

10.4.2 the Indemnitor will not, except with the written consent of the Indemnitee, such consent not to be unreasonably withheld, delayed or conditioned, consent to the entry of any judgment or enter into any settlement provided always, that if the Indemnitee shall not consent to such entry of judgment or settlement, and provided that such judgment or settlement does not involve an admission of liability on the part of the Indemnitee then the amount which the Indemnitee shall be entitled to recover from the Indemnitor pursuant to this Clause 10 shall be limited to the amount that they would have received if the action would otherwise have been settled.

10.4.3 The Indemnitee shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld, conditioned or delayed.

11. INSURANCE

11.1 Within [*] after the Effective Date, ProNAi shall put in place and thereafter maintain, at its own cost, [*] product/clinical trial liability insurance and general commercial liability insurance through a reputable insurance company, with respect to Licensed Products. ProNAi shall name CPF as an additional insured on such policy, and at CPF's request, ProNAi shall provide CPF with a certificate evidencing the coverage required hereby, and the amount thereof. Such insurance shall be maintained as follows: (a) at least [*] years following the expiration or termination of this Agreement with respect to general commercial liability insurance, and (b) at least [*] years following the last date of patient dosing for product/clinical trial liability insurance.

12. LIMITATION OF LIABILITY

12.1 Subject to Clause 12.2, neither Party nor their respective directors, officers, employees and agents shall have any liability under or in connection with this Agreement whether under statute or in tort (including but not limited to negligence), contract or otherwise in respect of: (i) any consequential or indirect loss; and/or (ii) any loss of goodwill, opportunity, profit or contract, in either case even if advised in advance of the possibility of such losses.

12.2 Nothing in this Agreement shall be construed as excluding or limiting the liability of any person for any liability which cannot be limited or excluded by law.

13. CONFIDENTIALITY

13.1 Each Party (the "**Receiving Party**") undertakes with each other Party (the "**Disclosing Party**") that it shall keep, and it shall procure that its respective directors, partners, officers, employees and agents (collectively, "**Representatives**") shall keep, secret and confidential all Confidential Information of the Disclosing Party and shall not publish or disclose the same or any part of the same to any person whatsoever other than:

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13.1.1 in the case of ProNAi to: (i) Sub-Licensees and Third Party Service Providers, subject to compliance with Clauses 3.4 and 3.6 respectively; (ii) any actual or prospective investors in, or acquirers of, ProNAi, including pursuant to obligations under applicable laws and regulations (in particular but without limitation those of the US Securities & Exchange Commission); (iii) Competent Authorities in the Territory as necessary in communications relating to the Licensed Patents and Licensed Products; (iv) potential Sub-Licensees and potential Third Party Service Providers, and (v) as reasonably necessary to exploit the licenses granted to ProNAi hereunder, provided that any such persons to whom disclosure is made under (i) through (v) have agreed to be bound by a legal obligation of confidentiality no less restrictive than that set forth in this Clause 13,;

13.1.2 in the case of each Party, to its Representatives directly or indirectly concerned in the exercise of the rights granted under this Agreement; and

13.1.3 in the case of CPF, (i) to CPF Reviewers and to any research institutions involved in the generation or development of the Licensed Intellectual Property pursuant to Clause 4.5, and (ii) to CPF's potential or actual investment bankers, acquirers, lenders, investors or collaborators, and (iii) legal advisors of any of the foregoing in (i) and (ii), provided that in each case any such persons or entities have agreed to be bound by a legal obligation of confidentiality no less restrictive than that set forth in this Clause 13.

13.2 The Parties agree that any information comprised in the Exclusively Licensed Intellectual Property shall be considered to be the Confidential Information of ProNAi as well as CPF (such information the "**Licensed Confidential Information**"). Consequently, except as set forth in Sections 3.3.2 and 27.4, CPF shall be bound by the confidentiality provisions in this Clause 13 in respect of such Licensed Confidential Information as though it had been disclosed to each of them by ProNAi.

13.3 Each Party shall ensure that each of its Representatives to whom any Confidential Information is disclosed shall previously have been informed of the confidential nature of the Confidential Information and shall have agreed to be bound by a legal obligation of confidentiality no less restrictive than that set forth in this Clause 13.

13.4 CPF shall, where it wishes to transfer Confidential Information of ProNAi to:

13.4.1 CPF Reviewers, provide ProNAi, upon reasonable notice, the opportunity to review and comment on any Confidential Information proposed to be disclosed to CPF Reviewers and shall give due consideration to any comments received from ProNAi. CPF recognises the need to protect the confidentiality of the chemical structures of Licensed Compounds. Notwithstanding the foregoing, CPF shall be permitted to disclose to any CPF Reviewers such Confidential Information as it may determine in its reasonable discretion to disclose. Such disclosure shall be made under the terms of a confidential disclosure agreement the confidentiality term of which shall be no less than ten (10) years.

13.4.2 any research institutions that have been involved in the generation or development of the Licensed Intellectual Property:

(a) be free to provide Confidential Information only to the extent that the Confidential Information relates solely to the revenues paid by ProNAi to CPF ("**Revenue Information**"); or

(b) only provide Confidential Information, which is not Revenue Information, having first obtained ProNAi's prior written consent to such transfer,

provided that CPF may only provide Confidential Information under this Clause 13.4.2 to such research institutions to the extent that CPF has a financial or other obligation to such research institution with respect to the creation of such Licensed Intellectual Property, and such Confidential Information is necessary to show compliance with such obligation.

13.5 The provisions of Clauses 13.1, 13.2 and 13.4 shall not apply to Confidential Information which:

13.5.1 the Receiving Party can demonstrate by reference to written records to have been in its possession (other than under an obligation of confidence to the Disclosing Party or to a Third Party) at the date of receipt;

13.5.2 the Receiving Party can demonstrate by reference to written records that it received from a Third Party without obligation of confidence to the Disclosing Party after receipt from the Disclosing Party;

13.5.3 enters the public domain otherwise than through a breach of any obligation of confidentiality owed to the Disclosing Party; or

13.5.4 the Receiving Party can prove it has independently developed without the use of the Disclosing Party's Confidential Information.

13.6 The Receiving Party may disclose Confidential Information to the extent that such disclosure is:

13.6.1 necessarily required of the Receiving Party by order of a Competent Authority or otherwise by applicable law; provided, that the Receiving Party shall, to the extent practicable in the time available and where legally permissible, first have given notice to the Disclosing Party and shall provide such assistance to the Disclosing Party as it may reasonably require in order for it to make an application to quash any such order or obtain a protective order requiring that the Confidential Information the subject of such order be held in confidence by such Competent Authority or, if disclosed, be used only for the purpose for which the order was issued; and provided further that if such order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such order shall be limited to that information that is legally required to be disclosed in response to such order;

13.6.2 made by the Receiving Party to a Patent authority as may be necessary or useful for the purposes of obtaining or enforcing a Licensed Patent (consistent with the terms and conditions of Clause 8), provided, however, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or

13.6.3 required with regard to the disclosure requirements of a national securities exchange or other stock market or of a related regulatory body on which the Receiving Party's securities are or are proposed to be traded, provided it has used reasonable endeavours in the time available to provide notice to the Disclosing Party of the terms of any such disclosure beforehand.

13.7 The Receiving Party agrees that the disclosure of the Disclosing Party's Confidential Information without the express written consent of the Disclosing Party may cause irreparable harm to the Disclosing Party, and that any breach or threatened breach of this Agreement by the Receiving Party may entitle the Disclosing Party to injunctive relief, in addition to any other legal remedies available to it, in any court of competent jurisdiction.

13.8 The provisions of this Clause 13 shall remain in force for a period of ten (10) years from the expiry or termination of this Agreement.

14. TERM AND TERMINATION

14.1 This Agreement will become effective on the Effective Date. Subject to the provisions of this Clause 14 it will remain effective in each country of the Territory until the expiry of the obligation upon ProNAi to pay royalties in relation to that country pursuant to this Agreement.

14.2 Without prejudice to any other rights of the Parties, this Agreement may be terminated by notice in writing:

14.2.1 by (a) ProNAi if CPF is in material breach of any of its obligations under this Agreement; or (b) CPF if ProNAi is in material breach of any of its obligations under this Agreement; and in both cases in the case of a remediable breach fails to remedy the breach within sixty (60) Business Days of written notice containing full particulars of the breach and requiring it to be remedied, provided that (i) this Agreement shall not terminate for breach until there has been a final determination pursuant to Clause 28 (including by way of settlement) of the existence of an uncured material breach and the terminating Party's right to terminate this Agreement (provided that following such final determination, this Agreement shall be deemed terminated and the breaching Party shall not be afforded any additional cure period), or the Parties mutually agree to such a termination upon expiration of the cure period, and (ii) this Agreement shall remain in force on its terms during any period when the existence of a material breach giving the right to terminate is in dispute; or

14.2.2 by either ProNAi on the one hand or CPF on the other forthwith if, in respect of either ProNAi on the one hand or CPF on the other a voluntary arrangement is proposed or approved or an administration order is made, or a receiver or administrative receiver is appointed of any of the other Party's assets or undertakings or a winding-up resolution or petition is passed (otherwise than for the purpose of solvent reconstruction or amalgamation, in particular with respect to any reorganisation of the structure of the relevant Party) or if any circumstances arise which entitle a court or a creditor to appoint a receiver, administrative receiver or administrator or make a winding-up order or similar or equivalent action is taken by the relevant Party by reason of its insolvency or in consequence of debt or is taken against the relevant Party and is not dismissed within ninety (90) Business Days; or

14.2.3 by CPF upon thirty (30) days written notice to ProNAi, if ProNAi challenges or seeks to challenge the validity of any of the Licensed Patents and ProNAi shall forthwith in writing notify to CPF any decision to challenge the Licensed Patents which it makes or of which it becomes aware; provided that, for clarity, the foregoing right to terminate shall not apply solely to the extent ProNAi is legally obligated to assist in any Third Party challenge (including through a subpoena), and assists in such challenge solely to the extent legally required to do so;

14.2.4 by CPF forthwith in the event of a change of Control of ProNAi where the new Controlling party is a Tobacco Party; or

14.2.5 in accordance with Clause 4.6; or

14.2.6 by ProNAi without cause by ninety (90) days written notice to CPF.

14.3 This Agreement shall terminate automatically upon the termination of the Upstream Licence Agreement. CPF shall promptly provide written notice to ProNAi following any receipt from CRUK and/or ICR of any notice of termination under the Upstream Licence Agreement. Notwithstanding the foregoing, provided the termination of the Upstream Licence Agreement was not caused by a breach of ProNAi's obligations under this Agreement, CRT and ICR are required, pursuant to the terms of the Upstream Licence

Agreement, to grant to ProNAi a licence on materially the same terms to that contained in this Agreement (a "**Substituted Sublicense**"), save that this shall not result in CRT or ICR taking on any more onerous obligations or assuming any liability greater than its obligations to CPF pursuant to the Upstream Licence Agreement. Pursuant to the terms of the Upstream Licence Agreement, CRT is required to continue to pay to CPF such sums as it would have received under the terminated sub-licence less the amount which the CPF would have had to pay CRT pursuant to the Upstream Licence Agreement and less any Patent Costs or other costs which would have been borne by CPF, but for the termination of the Upstream Licence Agreement. For the avoidance of doubt, expiration of the Upstream Licence Agreement consequent upon the expiry of the Term of the Upstream Licence Agreement shall not result in the automatic termination of any sub-licence.

15. EFFECTS OF TERMINATION

15.1 Upon the termination (but not expiration) of this Agreement for any reason:

15.1.1 payment of royalties and all other sums (including milestones, if applicable) due to CPF through the effective date of termination shall become due to CPF upon the effective date of termination of this Agreement, and shall be payable no later than [*] following such termination;

15.1.2 ProNAi shall, [*] of the effective date of termination of this Agreement provide CPF with a final written statement detailing, in respect of the time elapsed since the last report under Clause 6.6, the matters set out in Clause 6.6;

15.1.3 ProNAi shall consent to the revocation of any confirmatory Patent licence relating to the Licensed Patents granted pursuant to Clause 8.10 and the cancellation of the Registration of any such licence in any register;

15.1.4 ProNAi shall promptly transfer to CPF (or any person nominated by CPF) any and all documents and information in ProNAi's control or possession relating to the Licensed Patents and CPF may assume responsibility for the prosecution and maintenance of the same;

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15.1.5 the licences granted to ProNAi pursuant to Clause 3 shall terminate forthwith, and ProNAi shall have no further rights in or to the Licensed Intellectual Property pursuant to this Agreement. Unless ProNAi is granted a direct sublicence by CRT following such termination, ProNAi (and its Affiliates and Sub-Licensees) may, upon request and with CPF's prior written consent (which may be withheld at CPF's discretion), for a period [*] following such termination, continue to sell off any inventory of finished Licensed Products existing as of the effective date of such termination, provided that ProNAi shall continue to account to CPF for any royalty owed on Net Sales of such Licensed Products. Upon the expiration of such [*], or promptly following the effective date of such termination (if CPF does not give its consent to such inventory sell off), ProNAi shall, at CPF's election, transfer to CPF or destroy, and shall cause its Affiliates and Sub-Licensees (to the extent such Sub-Licensees do not retain their sublicenses following such termination), to transfer to CPF or to destroy, at CPF's reasonable expense, all inventory of Licensed Products in ProNAi's possession, provided that if CPF requests a transfer of such inventory, CPF shall also reimburse ProNAi for ProNAi's reasonable cost of manufacture (or purchase from a Third Party) of such inventory of Licensed Products, in addition to the costs of such transfer.

15.1.6 ProNAi shall, at the request and option of CPF, return or destroy the Licensed Know How and the Licensed Materials in its possession or control;

15.1.7 In the event that ProNAi had signed a sub-licence, such sub-licence shall terminate and Clause 3.5.1 shall apply. The principles in Clauses 6.3 through6.6 and 7 shall apply to CPF as though it were substituting ProNAi in those Clauses where ProNAi was the beneficiary of those Clauses under such terminated sublicense; and

15.1.8 save where this Agreement is terminated by ProNAi pursuant to Clause 14.2.1, in the event that CPF desires to proceed with the development and/or exploitation of any Licensed Products:

15.1.9 ProNAi hereby grants to CPF under the Arising Intellectual Property a perpetual, irrevocable, fully-paid, sub-licensable, worldwide, non-exclusive licence to research, develop, make, have made, market, use and sell Licensed Products to the extent falling within the scope of the Arising Intellectual Property.

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15.1.10 Solely in the case of termination by ProNAi pursuant to Clause 14.2.6, or by CPF in accordance with Clause 14.2.1, 14.2.2, 14.2.3, 14.2.4 or 14.2.5, ProNAi shall, at CPF's request and cost, transfer to CPF (or its nominee) as soon as practicable any Registrations, Price Approvals and other permits and applications relating to Licensed Products; and cancel, and consent to the cancellation by CPF, of the Registration of this Licence Agreement with any national Patent registry or other relevant Competent Authority; and

15.1.11 ProNAi shall, at CPF's cost, within fourteen (14) days of the date of termination of this Agreement disclose to CPF (or its nominee) all Arising Intellectual Property.

15.2 In the event that CPF does not take up the licence set out in Clause 15.1, the right to take such licence shall pass to ICR or CRT *mutatis mutandis.*

15.3 The termination of this Agreement howsoever arising will be without prejudice to the rights and duties of either Party accrued prior to termination. The following Clauses will continue to be enforceable notwithstanding termination: Clauses 1, 3.2, 3.5.1,6 (with respect to any payments owing as of the effective date of termination), 7, 8.9 (with respect to proceedings commenced as of the effective date of termination), 10, 11, 12, 13, 14.3, 15 and 18 to 29 inclusive.

16. FORCE MAJEURE

16.1 If a Party is unable to carry out any of its obligations under this Agreement due to Force Majeure (the "**Non-Performing Party**") this Agreement shall remain in effect but the Non-Performing Party's relevant obligations under this Agreement and the relevant obligations of the other Parties (the "**Innocent Parties**") under this Agreement shall be suspended for the duration of the circumstance of Force Majeure provided that:

16.1.1 the suspension of performance is of no greater scope than is required by the Force Majeure;

16.1.2 the Non-Performing Party gives the Innocent Parties prompt notice

describing the circumstance of Force Majeure, including the nature of the occurrence and its expected duration, and continues to furnish regular reports during the period of Force Majeure;

16.1.3 the Non-Performing Party uses all reasonable efforts to remedy its inability to perform and to mitigate the effects of the circumstance of Force Majeure; and

16.1.4 as soon as practicable after the event which constitutes Force Majeure the Parties shall discuss how best to continue their operations as far as possible in accordance with this Agreement.

17. ASSIGNMENT AND SUB-CONTRACTING

17.1 This Agreement shall be binding upon and inure to the benefit of the Parties, their successors and assigns. This Agreement shall be assignable:

17.1.1 by a Party with the written consent of the other Parties; or

17.1.2 by a Party without the consent of the other Parties, to (a) an Affiliate, or (b) any successor to all or substantially all the assets of its business to which this Agreement relates.

17.2 CPF shall have the right to assign the right to receive income pursuant to this Agreement but shall not otherwise have the right to assign the benefit or burden of this Agreement.

18. NOTICES

18.1 All notices shall be in writing and sent by hand, email, or recorded delivery and shall be deemed to be properly served (i) if sent by hand, when delivered at the relevant address; (ii) if sent by recorded delivery, three (3) Business Days after posting; (iii) if sent by email, when transmitted, provided a confirmation of delivery is received, and shall be sent to the following addresses or email address as may be amended by the relevant Party in writing:

CPF:	[*]
Email:	[*]
For the attention of:	[*]
ProNAi:	ProNAi Therapeutics, Inc. 1000 Marina Blvd, Suite 450 Brisbane, CA 94005, U.S.A.
Email:	[*]
For the attention of:	[*]

19. VARIATION

19.1 No variation, modification, amendment, extension or release from any provision of this Agreement shall be effective unless it is in writing, signed by each of the Parties.

20. ENTIRE AGREEMENT

20.1 Each Party confirms that this Agreement (including all Schedules) represents the entire understanding, and constitutes the whole agreement, in relation to its subject matter and supersedes any previous agreement between the Parties with respect thereto PROVIDED that the confidentiality agreement entered into between the Parties on 30 September 2015 shall continue in full force and effect.

20.2 Each Party confirms that:

20.2.1 it has not relied on any representation or warranty or undertaking which is not contained in this Agreement; and

20.2.2 in any event, without prejudice to any liability for fraudulent misrepresentation or fraudulent misstatement, neither Party shall be under any liability or shall have any remedy in respect of misrepresentation or untrue statement unless and to the extent that a claim lies under this Agreement.

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21. FURTHER ASSURANCE

21.1 Each Party hereby undertakes to do all such other acts and things, and execute and provide all such documents at the other Party's request and cost as may be reasonably necessary or desirable to give effect to the purposes of this Agreement.

22. NO PARTNERSHIP

22.1 Nothing in the Agreement and no action taken by the Parties pursuant to this Agreement shall constitute or be deemed to constitute a partnership association, joint venture or other co-operative entity between the Parties and none of the Parties shall have any authority to bind any of the others in any way except as provided in this Agreement.

23. COSTS

23.1 Each Party shall bear its own legal costs, legal fees and other expenses incurred in the negotiation, preparation, execution and implementation of this Agreement and the documentation referred to herein.

24. WAIVER

24.1 No relaxation, forbearance, waiver or indulgence by either Party in enforcing any of the terms or conditions of this Agreement or the granting of time by either Party to the other shall prejudice, affect or restrict the rights and powers of such Party, unless contained in a writing signed by the Party charged with such waiver. The waiver of any breach of any term or any condition of this Agreement shall not be construed as a waiver of any subsequent breach of a term or condition of the same or of a different nature.

25. SEVERABILITY

25.1 If the whole or any part of this Agreement is or becomes or is declared illegal, invalid or unenforceable in any jurisdiction for any reason (including by reason of the provisions of any legislation and/or by reason of any court or Competent Authority):

25.1.1 in the case of the illegality, invalidity or unenforceability of the whole of this Agreement it shall terminate only in relation to the jurisdiction in question; or

25.1.2 in the case of the illegality, invalidity or unenforceability of a part of this Agreement that part shall be severed from this Agreement in the jurisdiction in question and that illegality, invalidity or unenforceability shall not in any way whatsoever prejudice or affect the remaining parts of this Agreement which shall continue in full force and effect and in no circumstances shall sums paid by ProNAi to CPF under this Agreement be repayable.

25.2 If in the reasonable opinion of a Party any severance under this Clause 25 materially affects the commercial basis of this Agreement, the Parties shall negotiate in good faith to modify the Agreement to preserve (to the extent possible) their original intent.

26. EXECUTION

26.1 This Agreement may be executed in any one or more number of counterpart agreements each of which, when executed, shall be deemed to form part of and together constitute this Agreement.

27. ANNOUNCEMENTS, PUBLICATIONS AND USE OF NAMES

27.1 Save as provided in Clause 27.2 neither Party shall make, or procure or permit the making of, any press release or other public announcement (including on any website or in any company publication) in relation to this Agreement without first obtaining the written approval of the other Party to any such release or announcement, which shall not unreasonably be withheld, conditioned or delayed.

27.2 ProNAi will prepare a press release to announce the execution of this Agreement and will provide it to CPF in advance of disclosure and will reasonably incorporate any comments provided by CPF. ProNAi acknowledges and agrees that pursuant to the Upstream Licence Agreement, the consent (not to be unreasonably withheld, delayed or conditioned) of CRT and ICR is required in relation to any press release that relates to the Upstream Licence Agreement, and accordingly, ProNAi shall provide the foregoing proposed press release to CPF in sufficient time for CPF to obtain the consent of ICR and CRT to such press release, and shall not disclose such press release in the absence of such consent. Either Party may disclose the foregoing press release. Any Party may make an announcement with respect to this Agreement or any ancillary matter if required by

law or the regulations of any stock exchange to which it is subject, without the other Party's consent provided it has used reasonable endeavours in the time available to consult with the other Party on the terms of any such announcement beforehand.

27.3 ProNAi shall: (i) for the period from the Effective Date, to a date which is eighteen (18) months after, ensure that the ICR's researchers shall be named as authors on the first publication of any Licensed Intellectual Property if required by, and in accordance with, customary standards of scientific attribution; and (ii) acknowledge ICR's involvement in the research and development of any Licensed Product (which, in the case of a Sub-Licensee is the subject of the sublicence) in any academic publication, other trade publication or press release relating to that Licensed Product provided always that ProNAi shall have no liability to CPF if, subject to ProNAi having taken the steps set out in the remainder of this Clause 27.3, the Sub-Licensee does not agree to the provisions of this Clause 27.3 or subsequently breaches these provisions. In the event of a breach by a Sub-Licensee of the provisions of this Clause 27.3, and on receipt of written notice from the CPF notifying ProNAi of such breach (which may be delivered by email), ProNAi hereby undertakes to notify the Sub-Licensee of such breach and to request future adherence to the terms of this Clause 27.3. No Party shall use the name or marks of any other (including CRUK), other than as provided in Clause 27.1 and 27.2 without the prior written consent of that Party which shall be at that Party's sole discretion.

27.4 CPF and ProNAi acknowledge the importance of publications to the academic standing of ICR. Any publication or presentation at an academic conference or in an academic journal in respect of the development of a Pre-Clinical Candidate, a Licensed Product or the results of any clinical trial for a Licensed Product, and any marketing materials (including flyers) produced by ProNAi referring to Licensed Product Development shall appropriately cite the contributions of all parties (including ICR) and CRUK and the researchers undertaking the research, using customary standards of scientific attribution. CPF shall provide ProNAi with any publication or presentation for an academic conference or in an academic journal at least thirty (30) days prior to submission for presentation or publication so that (a) Confidential Information of ProNAi (other than the Licensed Confidential Information) can be deleted and (b) Patent protection may be sought by ProNAi, if desired and applicable. If ProNAi notifies CPF within such period that it desires to file a Patent application on any inventions, then submission of such publication or presentation shall be delayed for an additional period of:

27.4.1 [*] days to the extent that the publication or presentation contains information which describes [*] within Exclusive Licensed Intellectual Property; or

27.4.2 [*] days where the publication or presentation contains information which relates to the Exclusive Licensed Intellectual Property, other than [*];

27.4.3 [*] days where the publication or presentation contains information which relates to [*]; and

27.4.4 no delay in the event that the publication or presentation only contains chemical structures and other materials and data which are already in the public domain,

provided that while such Patent application is prepared and filed, if no comments are provided during the applicable review period, the Parties will be free to make such presentation or publication without further obligation to the other Party. Following approval of any publication or presentation, the publishing Party shall be free to publish the content of the publication or presentation in any other format (including on its website) without referring such (subsequent) publication or presentation to the other Parties.

28. DISPUTE RESOLUTION AND GOVERNING LAW

28.1 In the event that a determination of the Expert is sought under this Agreement (and to the extent this Agreement expressly provides for the use of an Expert for the applicable dispute):

28.1.1 the opinion of that Expert (who shall act as an expert and not as an arbitrator) shall be final and binding on the Parties;

28.1.2 each Party shall make written submissions to the Expert and to the other Parties within [*] of the Expert's appointment;

28.1.3 each Party shall have [*] to respond to the other Parties' submissions;

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28.1.4 the Parties shall request that the Expert deliver his opinion within a further [*]; and

28.1.5 the costs associated with the appointment of the Expert shall be borne [*] or, if no such determination is made by the Expert, by [*].

28.2 It shall be a condition precedent to the commencement of any action in court or other tribunal (save an action for an interim injunction) in respect of any dispute relating to this Agreement that the Parties have sought to resolve the dispute by a Party notifying the other Parties in writing for resolution to the Executive Officers who shall meet (whether in person or via teleconference) within [*] of such notice to seek resolution in good faith. If the Executive Officers are unable to resolve the dispute at such meeting, any Party may pursue any remedy available to such Party at law or in equity, subject to the terms and conditions of this Agreement.

28.3 This Agreement shall be governed by and construed in accordance with the laws of England and Wales and the Parties agree, subject to Clauses 28.1 and 28.2, to submit to the exclusive jurisdiction of the English courts in respect of any dispute arising out of or in connection with this Agreement (except in respect of disputes under Clause 13 where jurisdiction is non-exclusive).

29. CONTRACTS (RIGHTS OF THIRD PARTIES) ACT 1999

29.1 No term of this Agreement is enforceable under the Contracts (Rights of Third Parties) Act 1999 by a person who is not a party to this Agreement. Notwithstanding the provisions of this Clause 29, the Parties shall be entitled to amend, suspend, cancel or terminate this Agreement or any part of it in accordance with Clause 19, without the consent of any third party including those referred to in this Clause 29, provided that such amendment, suspension, cancellation or termination does not affect adversely the rights of such Third Parties as referred to as enforceable by such Third Party in this Clause 29 (as of the Effective Date).

The Parties hereby execute this Agreement by their duly authorised Representatives:

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For **CRT PIONEER FUND LP acting by CRT Pioneer GP Limited its General Partner**

Signature: /s/ Ian Miscampbell

Name: Ian Miscampbell

Title: Director – CRT Pioneer GP Limited

For **PRONAI THERAPEUTICS, INC.**

Signature: /s/ Dr. Nick Glover

Name: Dr. Nick Glover

Title: President & CEO

SCHEDULE 1

LICENSED PATENTS

Client Ref	Application Number	Application Date	Publication No	Grant Date	Title
[*]	[*]	[*]	[*]	[*]	[*]

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SCHEDULE 2

LICENSED KNOW-HOW

SCHEDULE 2 PART A:

EXCLUSIVELY LICENSED KNOW-HOW

[*]

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SCHEDULE 2 PART B:

NON-EXCLUSIVELY

LICENSED KNOW-HOW

[*]

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SCHEDULE 3

LICENSED MATERIALS

SCHEDULE 3 PART A

EXEMPLIFIED COMPOUNDS

[*]

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SCHEDULE 3 PART B

UNEXEMPLIFIED COMPOUNDS

[*]

***Confidential Treatment Requested.**

SCHEDULE 3 PART C

NON-COMPOUND MATERIALS

[*]

***Confidential Treatment Requested.**

SCHEDULE 4

PRODUCT CTA TRANSFER ACTIVITIES

[*]

***Confidential Treatment Requested.**

SCHEDULE 5

CHK1 CLINICAL SOPS

[*]

***Confidential Treatment Requested.**

SCHEDULE 6

PAYMENT

	Payment (USD)
Signature Fee	$7,000,000
Transfer of CTAs	$2,000,000
Royalties	Equal to: [*]
[*]	[*]

In the event that a Milestone Payment becomes due for a Milestone Event under this Schedule 6, but one or more Milestone Payments tied to earlier stages in development of such Licensed Product were not paid, (for example if [*] occurs, but no milestone was paid in connection with [*]), then such Milestone Payment attached to the earlier Milestone Event shall become due and payable contemporaneously with the payment for such later Milestone Event.

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SCHEDULE 7

SUB-LICENCE PROVISIONS

1. If the Sub-Licensee has received an exclusive sublicence from ProNAi to develop treatments for Oncology Indications, then if the Sub-Licensee reasonably believes that pursuing an Oncology Indication is likely to result in a product which would offer no substantial benefit to the patient population over existing drugs, or drugs in development, for the Oncology Indications that the Licensed Product would be most suitable for, then in such circumstances the Sub-Licensee shall provide an Other Indication Notice to ProNAi (which shall provide such Other Indication Notice to CPF) provided that (a) nothing in the foregoing shall preclude the Sub-Licensee from pursuing development and commercialization of a Licensed Product in an Other Indication concurrently with development and commercialization of Licensed Products in an Oncology Indication, provided that Sub-Licensee complies with its obligations under such sublicense, including the obligations set forth in Paragraph 2 below, in an Oncology Indication, and (b) where such Sub-licensee is developing and commercializing Licensed Products in an Oncology Indication, and is proposing to cease or scale back development and commercialization in all Oncology Indications (such that such Sub-Licensee would no longer meet its obligations under Paragraph 2 below in an Oncology Indication) in order to progress development and commercialization in an Other Indication, [*] the Sub-Licensee shall [*] for an Oncology Indication. Specifically, such Sub-Licensee shall [*] with the purpose of either (i) [*] in Oncology Indications, or (ii) [*] (with respect to the [*]) and allow [*] (or any [*]) to [*] Oncology Indications, provided that (A) any products developed following and as a result of the grant of rights to CRT or CPF [*] and shall not be [*] Oncology Indication under this Agreement, and (B) [*] and (2) [*] or (3) the [*] in an Oncology Indication, [*] shall be amended such that [*] shall apply in each case thereafter with respect to [*]. If at the end of the [*] negotiation period, [*] believes there is [*] (which may involve [*]) to [*]. Following [*], the parties will [*]. If such [*] will [*], whether to [*].

2. Where applicable to the rights granted to a Sub-Licensee by ProNAi (i.e. based on the territory or scope of sublicence granted), the Sub-Licensee will use Commercially Reasonable Efforts to:

   - make each Licensed Product available for purchase throughout the United Kingdom

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within [*] months of such Licensed Product receiving a European wide Registration (if the European-wide Registration also applies to permit commercialization in the United Kingdom on substantially similar terms, without the requirement for further material regulatory activities or filings in order to commence such commercialization in the United Kingdom) or a United Kingdom-specific Registration for launch

- develop and commercialise in each of the Major Markets at least one Licensed Product with an application in an Oncology Indication;
- in the event that a Licensed Product is launched or ready to be launched in the United Kingdom which has received a European wide Registration (if the European-wide Registration also applies to permit commercialization in the United Kingdom on substantially similar terms, without the requirement for further material regulatory activities or filings in order to commence such commercialization in the United Kingdom) or a United Kingdom-specific Registration in respect of an Oncology Indication, and such Sub-Licensee is responsible for setting the price of such Licensed Product, the Sub-Licensee will ensure that such Licensed Product is made available throughout the United Kingdom [*];
- provide ProNAi with a Progress Report at least once every twelve (12) months;
- promptly respond to any reasonable queries that ProNAi may have following receipt of a Progress Report; and
- at ProNAi's request, meet, once per Year, with ProNAi (either in person or by teleconference if a face-to-face meeting is not practical) to discuss the content of a particular Progress Report.

4. The Sub-Licensee shall indemnify, defend and hold harmless CPF Indemnified Parties from and against any and all Third Party claims, demands, losses, damages, costs and expenses (including, without limitation, legal fees) arising from or in connection with the exercise by the Sub-Licensee or its permitted Sub-Licensee of the rights granted to it or the actions of the Sub-Licensee, or its permitted Sub-Licensee in relation to a Licensed Product.

5. Prior to a Sub-Licensee commencing any proceedings pursuant to Clause 8.8, the Sub-

Licensee shall enter into a separate agreement with each of CPF and CPF's licensors pursuant to which the Sub-Licensee shall indemnify the CPF Indemnitees, CRT, ICR Indemnities (as defined in the Licence and Collaboration Agreement dated 23 September 2013 entered into by CPF, CRT and ICR) in respect of any and all potential Third Party claims, demands, losses, damages, costs and expenses (including, without limitation, legal fees) which might arise directly or indirectly as a consequence of such proceedings being concluded successfully or unsuccessfully (including without limitation any anti-trust proceedings commenced by a Third Party (for example, alleging that the price of any Licensed Product has been kept artificially high through the maintenance of Patent Rights which are invalid and/or unenforceable for any reason)).

6. Promptly after receipt by CPF of any claim or alleged claim or notice of the commencement of any action, administrative or legal proceeding, or investigation to which the indemnity provided for in this Paragraph 6 may apply, CPF shall give written notice to the Sub-Licensee of such fact and the Sub-Licensee shall have the option to assume the defence thereof by election in writing within thirty (30) days of receipt of CPF notice. If the Sub-Licensee fails to make such election, the Indemnified Party may assume such defence and the Sub-Licensee will be liable for the legal and other expenses consequently incurred in connection with such defence. The Parties will co-operate in good faith in the conduct of any defence, will provide such reasonable assistance as may be required to enable any claim to be defended properly and the Party with conduct of the action shall promptly provide to the other Party copies of all correspondence and documents and notice in writing of the substance of all oral communications relating to such action.

7. Should a Sub-Licensee assume conduct of the defence:

- the Indemnified Party may retain separate legal advisers, at its sole cost and expense save that if the Sub-Licensee denies the applicability of the indemnity or reserves its position in relation to the same, the indemnity shall extend to the Indemnified Party's costs and expenses; and

- the Sub-Licensee will not, except with the written consent of the Indemnified Party, such consent not to be unreasonably withheld, delayed or conditioned, consent to the entry of any judgment or enter into any settlement provided

always, that if the Indemnified Party shall not consent to such entry of judgment or settlement, the amount which the Indemnified Party shall be entitled to recover from the Sub-Licensee pursuant to the sub-licence shall be limited to the amount for which the action would otherwise have been settled or compromised; and

- the Sub-Licensee shall not admit liability in respect of, or compromise or settle any such action without the prior written consent of the Sub-Licensee, such consent not to be unreasonably withheld, conditioned or delayed.

8. Reasonably prior to Commencement of any human being dosed with the Licensed Product, the Sub-Licensee shall put in place and thereafter maintain, at its own cost, comprehensive (in both nature and amount) product liability insurance and general commercial liability insurance through a reputable insurance company with respect to Licensed Products. At CPF's request, the Sub-Licensee shall provide CPF with a certificate evidencing the coverage required hereby, and the amount thereof and the noting of CPF's interest. Such insurance shall be maintained as follows: (a) for at least [*] years following the expiration or termination of this sub-licence with respect to general commercial liability insurance, and (b) for at least [*] years following the last date of patient dosing for product/clinical trial liability insurance.

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SCHEDULE 8

TARGET PATENT COUNTRIES

[*]

***Confidential Treatment Requested.**

SCHEDULE 9

DEVELOPMENT PLAN FOR CCT245737

[*]

***Confidential Treatment Requested.**

SCHEDULE 10

CONFIRMATORY PATENT LICENCE

THIS AGREEMENT is made the _____ day of _____ 201[●]

1) **CRT PIONEER FUND LP** (the "**CPF**"), a limited liability partnership established in England and Wales under number LP 14391 with registered office at 4 Claridge Court, Lower Kings Road, Berkhamsted, Hertfordshire, HP4 2AF, acting by its general partner, CRT Pioneer GP Limited, a company registered in England and Wales with registered number 07933818 whose registered office is at 4 Claridge Court, Lower Kings Road, Berkhamsted, Hertfordshire, HP4 2AF (the "**General Partner**"); and

2) **[INSERT NAME OF PRONAI]**, [a company registered in/incorporated in/ established under the laws of [●●●] under number [●●●] with registered office/principal place of business at [●●●] ("**ProNAi**").

RECITALS:

By an agreement (the "**Main Agreement**") dated _____ and made between CPF and ProNAi, CPF agreed for the consideration therein contained, among other things, to grant to ProNAi a licence under [*Country/region Patent No.* _____] (the "**Patent**") of which this Agreement is a confirmatory licence.

OPERATIVE PROVISIONS:

1. In pursuance of the Main Agreement and for the consideration referred to in the Main Agreement CPF hereby grants to ProNAi the **[exclusive]** licence from the _____ day of _____ 20__ to research, develop, use, keep, make, have made, import, sell and otherwise dispose of Licensed Products (as defined in the Main Agreement) in the Field (as defined in the Main Agreement) in the Territory (as defined in the Main Agreement) for the life of the Patent and subject to the provisions of the Main Agreement.

2. Subject to the provisions of the Main Agreement this Agreement shall terminate without notice in the event of the termination for any reason of the Main Agreement.

SCHEDULE 11

PHASE I TRIAL COSTS INCURRED BY CPF AS OF EFFECTIVE DATE

Phase I Trial Costs		£	
[*]			
[*]		[*]	
[*]		[*]	
[*]		[*]	
[*]		[*]	
[*]		[*]	
	[*]	[*]	
[*]			
[*]		[*]	
[*]			
[*]		[*]	
[*]		[*]	
	[*]	[*]	
	[*]	[*]	[*]
Balance of CPF Phase I Development Contribution payable by CPF under Clause 5.3		$	[*]

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EXHIBIT 31.1

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nick Glover, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ProNAi Therapeutics, Inc.;

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

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

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

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

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

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth 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.

Date: November 10, 2016

/s/ Nick Glover

Dr. Nick Glover
Chief Executive Officer
(Principal Executive Officer*)*

EXHIBIT 31.2

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sukhi Jagpal, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ProNAi Therapeutics, Inc.;

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

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

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

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

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

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth 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.

Date: November 10, 2016

/s/ Sukhi Jagpal
Sukhi Jagpal
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

I, Nick Glover, Chief Executive Officer of ProNAi Therapeutics, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2016 (Report), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: November 10, 2016

/s/ Nick Glover
Dr. Nick Glover
Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

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

I, Sukhi Jagpal, Chief Financial Officer of ProNAi Therapeutics, Inc. (Company), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2016 (Report), as filed with the Securities and Exchange Commission, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: November 10, 2016

/s/ Sukhi Jagpal
Sukhi Jagpal
Chief Financial Officer
(Principal Financial Officer)