

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 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: 001-37507

**NANTKWEST, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**3530 John Hopkins Court  
San Diego, California**

(Address of principal executive offices)

**43-1979754**

(I.R.S. Employer  
Identification No.)

**92121**

(Zip Code)

**(858) 633-0300**

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class  
**Common Stock, \$0.0001 par value**

Name of each exchange on which registered  
**NASDAQ Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

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

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

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

As of May 10, 2016, the registrant had 81,977,285 shares of common stock, par value \$0.0001 per share, outstanding.

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## PART I – FINANCIAL INFORMATION

## ITEM 1. FINANCIAL STATEMENTS.

NantKwest, Inc.  
Condensed Consolidated Balance Sheets  
(in thousands, except for share amounts)

	March 31, 2016 (Unaudited)	December 31, 2015
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 63,250	\$ 175,908
Prepaid expenses and other current assets	3,776	3,322
Marketable securities	158,509	118,310
Total current assets	225,535	297,540
Marketable securities, noncurrent	116,197	55,135
Property and equipment, net	7,156	5,523
Intangible assets, net	6,844	7,292
Other assets	1,696	1,359
Total assets	<u>\$ 357,428</u>	<u>\$ 366,849</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,105	\$ 2,085
Accrued expenses	4,716	2,575
Due to related parties	1,674	1,352
Other current liabilities	363	136
Total current liabilities	7,858	6,148
Build-to-suit liability, less current portion	2,451	2,468
Deferred rent	1,344	845
Deferred revenue	203	228
Deferred tax liability	1,072	1,165
Total liabilities	12,928	10,854
Commitments and contingencies (Note 6)		
Stockholders' equity		
Common stock, \$0.0001 par value; 500,000,000 shares authorized; 81,930,998 and 81,311,686 issued and outstanding as of March 31, 2016 and December 31, 2015	8	8
Additional paid-in capital	625,200	606,555
Accumulated other comprehensive income (loss)	318	(192)
Accumulated deficit	(281,026)	(250,376)
Total stockholders' equity	344,500	355,995
Total liabilities and stockholders' equity	<u>\$ 357,428</u>	<u>\$ 366,849</u>

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

NantKwest, Inc.  
Condensed Consolidated Statements of Operations  
(in thousands, except for share and per share amounts)  
(Unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2016</u>	<u>2015</u>
<b>Revenue</b>	\$ 6	\$ 120
Operating expenses:		
Research and development	4,944	603
Selling, general and administrative	26,651	31,618
Total operating expenses	<u>31,595</u>	<u>32,221</u>
<b>Loss from operations</b>	(31,589)	(32,101)
Other income (expense):		
Investment income, net	768	32
Change in fair value of warrant liability	—	(883)
Other income, net	28	104
Total other income (expense)	<u>796</u>	<u>(747)</u>
<b>Loss before income taxes</b>	(30,793)	(32,848)
Income tax (benefit) expense, net	(143)	1
<b>Net loss</b>	<u>\$ (30,650)</u>	<u>\$ (32,849)</u>
Net loss per share:		
Basic and diluted	\$ (0.38)	\$ (0.54)
Weighted average number of shares during the period:		
Basic and diluted	81,574,709	61,137,625

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

NantKwest, Inc.  
Condensed Consolidated Statements of Comprehensive Loss  
(in thousands)  
(Unaudited)

	Three Months Ended March 31,	
	2016	2015
Net loss	\$ (30,650)	\$ (32,849)
Other comprehensive income, net of income taxes:		
Net unrealized gain on available-for-sale securities	517	—
Reclassification of net realized gains on available-for-sale securities included in net income	(7)	—
Total other comprehensive income	510	—
Comprehensive loss	\$ (30,140)	\$ (32,849)

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

NantKwest, Inc.  
Condensed Consolidated Statement of Stockholders' Equity  
(in thousands, except for share amounts)  
(Unaudited)

	Common		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
<b>Balance at December 31, 2015</b>	81,311,686	\$ 8	\$ 606,555	\$ (192)	\$ (250,376)	\$ 355,995
Exercise of stock options	917,383	—	657	—	—	657
Stock-based compensation expense	—	—	20,535	—	—	20,535
Exercise of warrants	1,929	—	3	—	—	3
Repurchase of common stock	(300,000)	—	(2,550)	—	—	(2,550)
Other comprehensive loss, net	—	—	—	510	—	510
Net loss	—	—	—	—	(30,650)	(30,650)
<b>Balance at March 31, 2016</b>	<u>81,930,998</u>	<u>\$ 8</u>	<u>\$ 625,200</u>	<u>\$ 318</u>	<u>\$ (281,026)</u>	<u>\$ 344,500</u>

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

NantKwest, Inc.  
Condensed Consolidated Statements of Cash Flows  
(in thousands)  
(Unaudited)

	<u>Three Months Ended March 31,</u>	
	<u>2016</u>	<u>2015</u>
<b>Operating activities:</b>		
Net loss	\$ (30,650)	\$ (32,849)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	485	26
Stock-based compensation expense	20,535	24,523
Deferred income tax benefit	(145)	—
Change in value of warrant liability	—	883
Non-cash interest items	(295)	—
Loss incurred by Inex Bio	—	57
Loss on disposal of assets	15	—
Amortization of net premiums on marketable securities	426	—
Gain on sales of marketable securities	(46)	—
Gain on settlement of note payable	—	(133)
Changes in operating assets and liabilities:		
Accounts receivable	—	105
Prepaid and other current assets	(160)	71
Other assets	(337)	(87)
Accounts payable	(737)	99
Accrued expenses and other liabilities	1,236	(3)
Due to related parties	322	—
Deferred rent	500	—
Deferred revenue	(5)	(64)
Net cash used in operating activities	<u>(8,856)</u>	<u>(7,372)</u>
<b>Investing activities:</b>		
Purchases of property and equipment	(1,067)	(38)
Purchase of Inex Bio Inc., net of cash acquired	—	(1,818)
Purchases of marketable securities	(111,397)	—
Sales of marketable securities	10,552	—
Net cash used in investing activities	<u>(101,912)</u>	<u>(1,856)</u>
<b>Financing activities:</b>		
Payments on notes payable	—	(132)
Proceeds from exercise of stock options and warrants	660	110
Repurchase of common stock	(2,550)	—
Net cash used in financing activities	<u>(1,890)</u>	<u>(22)</u>
Net decrease in cash and cash equivalents	(112,658)	(9,250)
Cash and cash equivalents, beginning of period	175,908	59,104
Cash and cash equivalents, end of period	<u>\$ 63,250</u>	<u>\$ 49,854</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid during the period for:		
Income taxes	\$ 1	\$ 1
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Issuance of warrants in Inex Bio, Inc. acquisition	\$ —	\$ 5,170
Property and equipment purchases included in accounts payable and accrued expenses	\$ 1,074	\$ —
Unrealized gain on marketable securities	\$ 796	\$ —

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

**NantKwest, Inc.**  
**Notes to Unaudited Condensed Consolidated Financial Statements**  
**(in thousands, except share and per share amounts)**

**1. Description of Business and Basis of Presentation**

***Organization***

NantKwest, Inc. (the Company) was incorporated in Illinois on October 7, 2002 under the name ZelleRx Corporation. On January 22, 2010, the Company changed its name to Conkwest, Inc., and on July 10, 2015, the Company changed its name to NantKwest, Inc. The Company is a biotechnology company headquartered in San Diego, California with certain operations in Culver City, California. The Company is commercially developing targeted direct-acting immunotherapeutic agents for a variety of clinical conditions.

The Company holds the exclusive right to commercialize activated natural killer (aNK) cells, a commercially viable natural killer cell-line, and a variety of genetically modified derivatives capable of killing cancer and virally infected cells. The Company owns corresponding U.S. and foreign composition and methods-of-use patents and applications covering the clinical use of aNK cells as a therapeutic to treat a spectrum of clinical conditions.

The Company also licensed exclusive commercial rights to a portfolio of CD16 bearing aNK cells along with the corresponding U.S. and foreign composition and methods-of-use patents and applications covering the non-clinical use in laboratory testing of monoclonal antibodies as well as clinical use as a therapeutic to treat cancers in combination with antibody products. The Company has licensed or sub-licensed its cell lines and intellectual property to numerous pharmaceutical and biotechnology companies for such non-clinical uses.

The Company retains exclusive worldwide rights to clinical and research data, intellectual property and know-how developed with the Company's aNK cells, as well as the only clinical grade master cell bank.

***Unaudited Interim Financial Information***

The accompanying condensed consolidated balance sheet at March 31, 2016, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2016, the condensed consolidated statements of cash flows for the three months ended March 31, 2016, and the condensed consolidated statement of stockholders' equity for the three months ended March 31, 2016, have been prepared by the management of Company and have not been audited. These financial statements have been prepared on the same basis as the audited consolidated financial statements for the fiscal year ended December 31, 2015 and, in the opinion of management, include all adjustments (consisting only of normal recurring adjustments) necessary for a fair statement of the Company's results for the periods presented. These financial statements should be read in conjunction with the financial statements and notes thereto for the fiscal year ended December 31, 2015 included in the Company's Annual Report on Form 10-K. Interim operating results are not necessarily indicative of operating results for the full year. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by accounting principles generally accepted in the United States of America (GAAP).

***Principles of Consolidation***

The Company's condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, Inex Bio, Inc., and have been prepared in accordance with GAAP. All intercompany amounts have been eliminated.

***Liquidity***

As of March 31, 2016, the Company had an accumulated deficit of approximately \$281.0 million. The Company also had negative cash flow from operations of approximately \$8.9 million during the three months ended March 31, 2016. The Company expects that it will likely need additional capital to further fund development of, and seek regulatory approvals for, its product candidates, and begin to commercialize any approved products.



The Company is currently focused primarily on the development of immunotherapeutic treatments for cancers and debilitating viral infections using targeted cancer killing cell lines, and believes such activities will result in the Company's continued incurrence of significant research and development and other expenses related to those programs. If the clinical trials for any of the Company's product candidates fail or produce unsuccessful results and those product candidates do not gain regulatory approval, or if any of the Company's product candidates, if approved, fails to achieve market acceptance, the Company may never become profitable. Even if the Company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. The Company intends to cover its future operating expenses through cash and cash equivalents and marketable securities on hand and through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional financing may not be available to the Company when needed and, if available, financing may not be obtained on terms favorable to the Company or its stockholders.

While the Company expects its existing cash and cash equivalents and marketable securities will enable it to fund operations and capital expenditure requirements for at least the next 24 months, it may not have sufficient funds to reach commercialization. Failure to obtain adequate financing when needed may require the Company to delay, reduce, limit or terminate some or all of its development programs or future commercialization efforts or grant rights to develop and market product candidates that the Company might otherwise prefer to develop and market itself which could adversely affect the Company's ability to operate as a going concern. If the Company raises additional funds from the issuance of equity securities, substantial dilution to existing stockholders may result. If the Company raises additional funds by incurring debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict the Company's ability to operate its business.

## **2. Summary of Significant Accounting Policies**

With the exception of the preclinical and clinical trial accrual policy discussed below, there have been no significant changes to the items that the Company disclosed as its summary of significant accounting policies in the Annual Report on Form 10-K for the year ended December 31, 2015.

### ***Preclinical and Clinical Trial Accruals***

As part of the process of preparing the financial statements, the Company is required to estimate expenses resulting from obligations under contracts with vendors, clinical research organizations and consultants. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

The Company estimates clinical trial and research agreement related expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on the Company's behalf. In accruing clinical and research related fees, the Company estimates the time period over which services will be performed and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

### ***Use of Estimates***

The preparation of condensed consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make certain 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 revenues and expenses during the reporting period. On an ongoing basis, the Company evaluates its estimates, including those related to the valuation of warrants, stock-based compensation, the valuation allowance for deferred tax assets, preclinical and clinical trial accruals, and the valuation of build-to-suit lease assets. The Company bases its estimates on historical experience and on various other market-specific and relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ from those estimates.

### ***Basic and Diluted Net Loss per Share of Common Stock***

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted loss per share is computed similarly to basic loss per share except that the denominator is increased to include the number of additional shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted loss per share as their effect is anti-dilutive. The following table details those securities that have been excluded from the computation of potentially dilutive securities:

	As of March 31,	
	2016	2015
Outstanding options	7,788,883	9,257,996
Outstanding restricted stock units	1,329,438	—
Outstanding warrants	17,817,687	22,610,078
Total	<u>26,936,008</u>	<u>31,868,074</u>

Amounts in the table above reflect the common stock equivalents of the noted instruments.

### Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2016-02, or ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize assets and liabilities for operating leases with lease terms greater than twelve months in the balance sheet. The update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-02 on its consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU 2016-09, *Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, as part of the initiative to reduce complexity in accounting standards. The areas for simplification in ASU 2016-09 involve several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, or classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2016-09 on its consolidated financial statements and disclosures.

### 3. Financial Statement Details

#### Prepaid Expenses and Other Current Assets

As of March 31, 2016 and December 31, 2015, prepaid expenses and other current assets were made up of (in thousands):

	March 31, 2016 (Unaudited)	December 31, 2015
Interest receivable - marketable securities	\$ 1,206	\$ 911
Prepaid services	1,182	631
Prepaid license fees	505	101
Prepaid legal fees	350	350
Prepaid insurance	298	466
Due from related parties (Note 7)	45	217
Tax refund receivable	—	646
Other	190	—
	<u>\$ 3,776</u>	<u>\$ 3,322</u>

**Property and Equipment, Net**

As of March 31, 2016 and December 31, 2015, property and equipment was made up of (in thousands):

	March 31, 2016 (Unaudited)	December 31, 2015
Construction in progress	\$ 6,753	\$ 5,136
Equipment	297	241
Leasehold improvements	182	182
Furniture & fixtures	123	125
Software	4	6
	<u>7,359</u>	<u>5,690</u>
Accumulated depreciation	(203)	(167)
	<u>\$ 7,156</u>	<u>\$ 5,523</u>

Construction in progress includes the estimated fair market value of the building under the Company's build-to-suit lease for \$2.7 million of which the Company is the "deemed owner" for accounting purposes only. See Note 6.

**Intangible Assets**

As of March 31, 2016 and December 31, 2015, intangible assets were made up of (in thousands):

	March 31, 2016 (Unaudited)	December 31, 2015
Technology license*	\$ 8,636	\$ 8,636
Less accumulated amortization	(1,792)	(1,344)
	<u>\$ 6,844</u>	<u>\$ 7,292</u>

\*Inclusive of \$1.5 million intangible asset related to the deferred tax liability, which is not amortized.

Amortization expense was \$0.4 million, and \$0 for the three months ended March 31, 2016 and 2015, respectively. Amortization for the Company's technology license is included in research and development expense on the condensed consolidated statement of operations.

**Other Assets**

As of March 31, 2016 and December 31, 2015, other assets were made up of (in thousands):

	March 31, 2016 (Unaudited)	December 31, 2015
Equipment not placed in service	\$ 609	\$ 624
License fees	423	—
Software license and implementation costs	415	391
Security deposit	249	344
	<u>\$ 1,696</u>	<u>\$ 1,359</u>

## Accrued Expenses

As of March 31, 2016 and December 31, 2015, accrued expenses were made up of (in thousands):

	March 31, 2016 (Unaudited)	December 31, 2015
Accrued bonuses	\$ 1,801	\$ 1,359
Accrued construction costs	992	132
Accrued compensation	828	348
Accrued professional and service fees	702	367
Accrued clinical trials	181	—
Accrued franchise and property taxes	81	225
Other	131	144
	<u>\$ 4,716</u>	<u>\$ 2,575</u>

## Investment Income, Net

Net investment income includes interest income from all bank accounts as well as marketable securities, net realized gains or losses on sales of investments and the amortization of the premiums and discounts of the investments and is as follows for the three months ended March 31, 2016 and 2015 (in thousands).

	Three Months Ended March 31,	
	2016	2015
Interest income	\$ 1,193	\$ 32
Investment amortization accretion expense, net	(426)	—
Net realized gains on investments	1	—
	<u>\$ 768</u>	<u>\$ 32</u>

Interest income includes interest from the Company's bank deposits. The Company did not recognize an impairment loss on any investments during the three months ended March 31, 2016 and 2015.

## 4. Cash Equivalents and Marketable Securities

As of March 31, 2016, all of the Company's marketable securities are classified as available-for-sale and are scheduled to mature within 3.6 years. At March 31, 2016, the detail of the Company's cash equivalents and marketable securities is as follows (in thousands):

	March 31, 2016			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Commercial paper	\$ 28,053	\$ 17	\$ —	\$ 28,070
Government sponsored securities	37,158	12	—	37,170
Corporate debt securities	111,315	75	(22)	111,368
Foreign government bonds	6,911	5	(3)	6,913
Current portion	183,437	109	(25)	183,521
Noncurrent:				
Government sponsored securities	17,039	68	—	17,107
Corporate debt securities	94,619	470	(15)	95,074
Foreign government bonds	4,009	7	—	4,016
Noncurrent portion	115,667	545	(15)	116,197
Total	<u>\$ 299,104</u>	<u>\$ 654</u>	<u>\$ (40)</u>	<u>\$ 299,718</u>

The cash equivalent portions included in the current fair values above are \$23.0 million and \$2.0 million for government sponsored securities and corporate debt securities, respectively.

At March 31, 2016, 16 of the securities and bonds are in an unrealized loss position. No securities have been in an unrealized loss position for greater than 12 months. Available-for-sale investments that had been in an unrealized loss position for less than 12 months at March 31, 2016 are as follows (in thousands):

	March 31, 2016	
	Estimated Fair Value	Gross Unrealized Losses
Corporate debt securities	\$ 37,658	\$ (37)
Foreign government bonds	1,894	(3)
<b>Total</b>	<b>\$ 39,552</b>	<b>\$ (40)</b>

The Company evaluated its securities for other-than-temporary impairment and concluded that the decline in value was primarily caused by current economic and market conditions. The Company does not intend to sell the investments and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases. Therefore, the Company did not recognize any other-than-temporary impairment loss during the three months ended March 31, 2016.

## 5. Fair Value Measurements

In accordance with the authoritative guidance for financial assets and liabilities measured at fair value on a recurring basis (ASC Topic 820), the Company prioritizes the inputs used to measure fair value from market-based assumptions to entity specific assumptions as follows:

- Level 1—Inputs based on quoted market prices for identical assets or liabilities in active markets at the measurement date.
- Level 2—Observable inputs other than quoted prices in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- Level 3— Inputs which reflect management’s best estimate of what market participants would use in pricing the asset or liability at the measurement date. The inputs are unobservable in the market and significant to the instruments valuation.

The following table presents the Company’s hierarchy for its assets measured at fair value on a recurring basis as of March 31, 2016 and December 31, 2015:

	Fair Value Measurements at March 31, 2016			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
<b>Current:</b>				
Cash and cash equivalents*	\$ 25,011	\$ —	\$ 25,011	\$ —
Commercial paper	28,070	—	28,070	—
Government sponsored securities	14,159	—	14,159	—
Corporate debt securities	109,368	—	109,368	—
Foreign government bonds	6,913	—	6,913	—
<b>Noncurrent:</b>				
Government sponsored securities	17,107	—	17,107	—
Corporate debt securities	95,074	—	95,074	—
Foreign government bonds	4,016	—	4,016	—
<b>Total assets measured at fair value</b>	<b>\$ 299,718</b>	<b>\$ —</b>	<b>\$ 299,718</b>	<b>\$ —</b>

\*This amount excludes \$38.2 million in depository institutions which are classified as Level 1 assets.

	Fair Value Measurements at December 31, 2015			
	Total	Level 1	Level 2	Level 3
<b>Assets:</b>				
<b>Current:</b>				
Cash and cash equivalents*	\$ 18,039	\$ —	\$ 18,039	\$ —
Commercial paper	24,917	—	24,917	—
Corporate debt securities	86,450	—	86,450	—
Foreign government bonds	6,943	—	6,943	—
<b>Noncurrent:</b>				
Corporate debt securities	51,131	—	51,131	—
Foreign government bonds	4,004	—	4,004	—
Total assets measured at fair value	<u>\$ 191,484</u>	<u>\$ —</u>	<u>\$ 191,484</u>	<u>\$ —</u>

\*This amount excludes \$157.9 million in depository institutions which are classified as Level 1 assets.

## 6. Commitments and Contingencies

### Contingencies

In March 2009, the Company received a final rejection in one of the Company's original patent applications pertaining to certain limited methods of use claims for NK-92 from the U.S. Patent and Trademark Office (the USPTO) (but the USPTO allowed claims on all of the other proposed claims, including other methods of use). The Company appealed this decision with the USPTO Board of Appeals and, in the fall of 2013, the Board of Appeals reversed the Examiner's rejection of the claim to certain limited methods of use with NK-92, but affirmed the Examiner's rejection of the remaining patent claims. In December 2013, the Company brought an action in the U.S. District Court for the Eastern District of Virginia to review the decision of the USPTO as the Company disagreed with the decision as to the certain limited non-allowed claims. On September 2, 2015, the U.S. District Court granted the USPTO's motion for summary judgment. The Company is in the process of appealing the decision. Based on the information available at present, the Company cannot reasonably estimate a range of loss for this action. Accordingly, no liability associated with this action has been accrued. The Company is expensing legal costs associated with defending this litigation as the costs are incurred.

### Securities Litigation

In March 2016, a securities class action complaint was filed in federal district court in California against the Company related to the recently announced restatement of certain interim financial statements for the periods ended June 30, 2015 and September 30, 2015. The case, *Sudunagunta v. NantKwest, Inc., et al.*, is currently pending before the United States District Court for the Central District of California. The complaint names the Company and certain of its current and former officers and directors, as defendants. The complaint alleges that the defendants misrepresented material facts and/or mislead investors regarding the errors in the consolidated financial statements related to stock-based awards to the chairman and chief executive officer (CEO) and build-to-suit lease accounting related to one of the Company's research and development and good manufacturing practices facilities, and regarding the lack of effective internal financial controls. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaint seeks unspecified damages, costs and attorneys' fees, and equitable/injunctive or other relief. Management intends to vigorously defend these proceedings. At this time, the Company cannot predict how the Court will rule on the merits of the claims and/or the scope of the potential loss in the event of an adverse outcome. Therefore, based on the information available at present, the Company cannot reasonably estimate a range of loss for this action. Should the Company ultimately be found liable, the liability could have a material adverse effect on the Company's results of operations for the period or periods in which it is incurred.

### Contractual Obligations - Leases

The Company leases: (i) office space in Cardiff-by-the-Sea, California; (ii) a research facility in Boston, Massachusetts on a month-to-month basis; (iii) a research facility in Woburn, Massachusetts (discussed further below) that will replace the Boston facility once it is ready for occupation; (iv) office space in Cary, North Carolina; (v) a research and manufacturing facility in San Diego, California and; (v) office and research space in Culver City, California from a related party (Note 7).

In March 2016, the Company entered into a lease agreement for an approximately 7,893 square foot facility in Woburn, Massachusetts for a research and development laboratory, related office and other related uses. The base rent is \$0.2 million per year with a \$1 per square foot annual increase on each anniversary date.

In March 2016, the Company extended the lease on the Cardiff-by-the-Sea, California office space until August 31, 2018. The current annual lease payment is \$0.1 million, which will increase to \$0.2 million and \$0.2 million at September 1, 2016 and 2017, respectively.

In November 2015, the Company entered into a facility license agreement with NantWorks, LLC (NantWorks), a related party, for office space in Culver City, California, which is to be converted to a research and development laboratory and a Good Manufacturing Practices (GMP) laboratory. The license was effective in May 2015 and extends through December 2020. The annual license fee is \$0.6 with annual increases of 3% beginning in January 2017.

The Company is responsible for costs to build out the laboratory and has incurred costs of approximately \$3.2 million as of March 31, 2016, which is reflected in construction in progress on the condensed consolidated balance sheet. Additionally, in order for the facility to meet the Company's research and development and GMP laboratory specifications, the Company made structural changes as part of the conversion from office to laboratory space, and as a result, the Company has concluded that it was the "deemed owner" of the building (for accounting purposes only) during the construction period. Accordingly, the Company recorded a non-cash build-to-suit lease asset of \$2.7 million, representing its estimate of the fair market value of the building, and a corresponding construction build-to-suit lease liability, recorded as a component of other current and non-current liabilities on the condensed consolidated balance sheet as of March 31, 2016.

Upon completion of construction of this facility, the Company will evaluate the de-recognition of the asset and liability under the provisions of ASC Subtopic 840-40, Leases - Sale-Leaseback Transactions. However, if the Company does not comply with the provisions needed for sale-leaseback accounting, the lease will be accounted for as a financing obligation and lease payments will be attributed to (1) a reduction of the principal financing obligation; (2) imputed interest expense; and (3) land lease expense (which is considered an operating lease and a component of research and development expenses) representing an imputed cost to lease the underlying land of the facility. In addition, the underlying building asset will be depreciated over the building's estimated useful life which is estimated at 39 years. At the conclusion of the lease term, the Company would de-recognize both the net book values of the asset and financing obligation.

The Company recognizes rent expense under its operating leases on a straight-line basis. Rent expense for the three months ended March 31, 2016 and 2015 was \$0.7 million and \$0.1 million, respectively.

### **Commitments**

The Company has not entered into any new significant contracts during the three months ended March 31, 2016.

### **7. Related Party Agreements**

The Company's chairman and CEO founded and has a controlling interest in NantWorks, which is a collection of multiple companies in the healthcare and technology space. The Company has entered into arrangements with NantWorks and certain affiliates of NantWorks, as described below, to facilitate the development of new genetically modified NK cells for the Company's product pipeline.

In March 2016, NantBioScience, Inc. (NantBioScience), a NantWorks company, and the National Cancer Institute entered into a cooperative research and development agreement. The agreement covers NantBioScience and its affiliates, including the Company. Under the agreement, the parties will collaborate on the preclinical and clinical development of proprietary recombinant NK cells and monoclonal antibodies in monotherapy and in combination immunotherapies. The Company expects to benefit from the preclinical and clinical research conducted during the first year under this agreement and is providing the first year of funding under the five-year agreement. In April 2016, the Company paid \$0.6 million to the National Cancer Institute as a prepayment for this first year of funding. The Company will recognize research and development expense ratably over a 12-month period.

Under the NantWorks shared services agreement executed in November 2015, but effective May 2015, NantWorks provides corporate, general and administrative, manufacturing strategy, regulatory and clinical trial strategy and other support services, and the Company is charged for the services at cost plus reasonable allocations for indirect costs that relate to the employees providing the services. For the three months ended March 31, 2016, the Company recorded \$0.8 million to selling, general and administrative expense and \$0.3 million to research and development expense under this arrangement on the condensed consolidated statement of operations. The Company owed NantWorks \$1.5 million for all agreements between the two affiliates at March 31, 2016, which is included in due to related parties on the condensed consolidated balance sheet.

Under the November 2015 facility license agreement with NantWorks for office and laboratory space, the Company recorded rent expense of \$0.1 million for the three months ended March 31, 2016, which is included in research and development expense on the condensed consolidated statement of operations. The Company is responsible for costs to build out the laboratory and has incurred costs of approximately \$3.2 million as of March 31, 2016, which is reflected in property and equipment, net on the condensed consolidated balance sheet.

Under the June 2015 agreement with NantOmics, LLC (NantOmics) to obtain genomic sequencing and proteomic analysis services, as well as related data management and bioinformatics services, exclusively from NantOmics, the Company incurred \$0.1 million of cost in the three months ended March 31, 2016, which is shown as research and development expense on the condensed consolidated statement of operations. The Company is obligated to pay NantOmics a fixed, per sample fee, determined based on the type of services being provided. The agreement has an initial term of five years and renews automatically for successive one year periods, unless terminated earlier. The Company owed NantOmics \$0.2 million at March 31, 2016, which is included in due to related parties on the condensed consolidated balance sheet.

## **8. Spinout of Brink Biologics and Coneksis**

On June 9, 2015, the Company spun out its business related to testing and diagnostic products and services into the entity, Brink Biologics, Inc. (Brink Biologics) in exchange for all of the issued and outstanding shares of Brink Biologics which were subsequently distributed by a dividend to the Company's stockholders. Under the spin-out arrangement, the Company transferred to Brink Biologics all of the Company's existing revenue-earning, non-exclusive license agreements that allow third parties to use the Company's cell lines and intellectual property for non-clinical laboratory testing. In addition, the Company transferred or licensed to Brink Biologics the Company's other assets associated with testing and diagnostics products and services. The Company granted to Brink Biologics worldwide, exclusive licenses to the use of certain cell lines limited to the field of *in vitro* and *in vivo* testing and diagnostic products and services, trademarks, intellectual property, and patents, including the Company's rights under its license agreement with Fox Chase Cancer Center. As part of the agreement, the Company also has a non-exclusive license to any results and data arising from Brink Biologics' use of the Company's cell lines and intellectual property for the Company's use for internal research purposes and outside of Brink Biologics' field. In consideration for the license grants, Brink Biologics is obligated to pay the Company a low single-digit royalty on amounts received for the sale of licensed products and services, as well as a low single-digit percentage share of other revenue received by Brink Biologics from the grant of sublicenses under the Company's rights. For the three months ended March 31, 2016, the Company recorded \$1,400 in revenue for royalties. Brink Biologics and the Company have the right to terminate the license agreement under certain conditions. Also, as part of the spin-out arrangement, the Company has agreed to provide certain services to Brink Biologics for a transitional period on a fee-for-service basis. In the three months ended March 31, 2016, the Company recorded \$7,000 for services provided to Brink Biologics, which is included in other income on the condensed consolidated statement of operations.

On June 9, 2015, the Company spun out its business related to veterinary oncology into the entity, Coneksis in exchange for all of the issued and outstanding shares of Coneksis which were subsequently distributed by a dividend to our stockholders. In connection with the spin-out arrangement, the Company granted to Coneksis worldwide, exclusive licenses for use of certain cell lines in the field of veterinary medical research and therapeutics, trademarks, intellectual property, and patents, including the Company's rights under its license agreement with Fox Chase Cancer Center. As part of the agreement, the Company also has a non-exclusive license to any results and data arising from Coneksis' use of the Company's cell lines and intellectual property for the Company's use for internal research purposes and outside of Coneksis' field. In consideration for the license grants, Coneksis is obligated to pay the Company a single-digit royalty on amounts received for the sale of licensed products and services, as well as a single-digit percentage share of other revenue received by Coneksis from the grant of sublicenses under the Company's rights. Coneksis and the Company have the right to terminate the license agreement under certain conditions. Also, as part of the spin-out arrangement, the Company has agreed to provide certain services to Coneksis for a transitional period on a fee-for-service basis. For the three months ended March 31, 2016, the Company recorded \$1,500 for services provided to Coneksis, which is included in other income on the condensed consolidated statement of operations. At March 31, 2016, Coneksis owes the Company \$8,000, which has been fully reserved.

The Company determined it has a variable interest in both Brink Biologics and Coneksis through its royalty agreements. Based upon the level of equity investment at risk, Brink Biologics and Coneksis are considered variable interest entities (VIEs). The Company considered whether it is the primary beneficiary of the Brink Biologics and Coneksis VIEs and required to consolidate the entities. As the Company does not control the research and development or the sales of the potential licensed or commercialized products, the Company does not direct the activities of Brink Biologics and Coneksis that most significantly impact their economic performance. Therefore, the Company determined that it is not the primary beneficiary of the entities and does not consolidate the Brink Biologics VIE and the Coneksis VIE.



## 9. Stockholders' Equity

*Stock Repurchase*—In November 2015, the board of directors approved a share repurchase program (2015 Share Repurchase Program) allowing the CEO or CFO, on behalf of the Company, to repurchase from time to time, in the open market or in privately negotiated transactions, up to \$50.0 million of the Company's outstanding shares of common stock, exclusive of any commissions, markups or expenses. The timing and amounts of any purchases will be based on market conditions and other factors, including price, regulatory requirements and other corporate considerations. The 2015 Share Repurchase Program does not require the purchase of any minimum number of shares and may be suspended, modified or discontinued at any time without prior notice. The Company expects to finance the purchases with existing cash balances.

During the three months ended March 31, 2016, 300,000 shares were repurchased at \$8.50 per share for a total of \$2.6 million. There were no commissions as it was a private repurchase at the then current market price. At March 31, 2016, \$47.4 million remained authorized for repurchase under the Company's 2015 Share Repurchase Program.

## 10. Stock-Based Compensation

### *Stock-Based Compensation*

The following table presents stock-based compensation included on the Company's condensed consolidated statements of operations (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2016</u>	<u>2015</u>
Stock-based compensation expense:		
Warrants for Class A common stock to an officer	\$ 12,090	\$ —
Warrants for Class A common stock to an officer and a director related to Inex Bio, Inc. acquisition	—	22,747
Employee stock options	4,893	1,088
Non-employee stock options	—	688
Employee restricted stock units	3,365	—
Non-employee restricted stock units	187	—
	<u>\$ 20,535</u>	<u>\$ 24,523</u>
Stock-based compensation expense in operating expenses:		
Research and development	\$ 262	\$ 189
Selling, general and administrative	20,273	24,334
	<u>\$ 20,535</u>	<u>\$ 24,523</u>

### *Stock Options*

The following table summarizes stock option activity under the equity incentive plans for the three months ended March 31, 2016 (in thousands, except for share and per share amounts):

	<u>Number of Shares</u>	<u>Weighted-Average Exercise Price</u>	<u>Aggregate Intrinsic Value</u>	<u>Weighted-Average Remaining Contractual Life (in years)</u>
Outstanding at December 31, 2015	8,777,893	\$ 5.36	\$ 116,273	7.2
Options forfeited	(71,627)	\$ 2.00		
Options exercised	(917,383)	\$ 1.21		
Outstanding at March 31, 2016	<u>7,788,883</u>	\$ 5.87	\$ 42,691	6.8
Vested and Exercisable at March 31, 2016	<u>4,844,757</u>			

The aggregate intrinsic value of stock options exercised during the three months ended March 31, 2016 was \$7.0 million.

The total unrecognized compensation cost related to non-vested stock options as of March 31, 2016 is \$18.9 million, which is expected to be recognized over a weighted-average period of 2.1 years.

## Restricted Stock Units

The following table summarizes the activity for restricted stock units under the 2015 Plan:

	Number of Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Unvested balance at December 31, 2015	1,129,638	\$ 20.51
Granted	234,800	\$ 8.60
Forfeited	(35,000)	\$ 17.13
Unvested balance at March 31, 2016	<u>1,329,438</u>	<u>\$ 18.50</u>

In March 2016, the Company granted 234,800 shares of restricted stock units of which 169,800 were granted to employees of the Company and 65,000 were granted to employees of related companies under the Company's shared services agreement with NantWorks (Note 7). As of March 31, 2016, there was \$12.2 million of unrecognized stock-based compensation expense related to restricted stock units that is expected to be recognized over a weighted-average period of 1.9 years. Of that amount, \$9.0 million of unrecognized expense is related to employee grants with a weighted-average period of 1.3 years and \$3.2 million of unrecognized expense is related to non-employee grants with a weighted-average period of 3.6 years and is impacted by periodic mark-to-market adjustments.

## Warrants

The following table summarizes the warrant activity for the three months ended March 31, 2016:

Outstanding at December 31, 2015	17,819,616
Warrants exercised	(1,929)
Outstanding at March 31, 2016	<u>17,817,687</u>
Vested and exercisable at March 31, 2016	<u>10,553,550</u>

## 11. Acquisition of Inex Bio, Inc.

In April 2012, the Company made a strategic decision to enter into a License Agreement with Inex Bio, Inc. (Inex Bio), a Republic of Korea corporation (the Inex License Agreement). Under the Inex License Agreement, the Company provided Inex Bio with an exclusive license to the Company's technology to be used in products only in certain Asian countries. In exchange for the Inex License Agreement, the Company received a \$0.3 million up-front license fee. In addition, the Company was eligible to receive milestone payments of up to \$0.8 million based upon completion of clinical trials and a 5% royalty on net sales of applicable products using the aNK cells. No milestone payments were due or received for the three months ended March 31, 2015.

In May 2012, the Company acquired 57,000 shares of Inex Bio for \$0.2 million, which represented 22.2% of the outstanding shares and 17.4% of the fully-diluted shares of Inex Bio. The Company accounted for its investment under the equity method. The Company reviewed its investment for impairment in accordance with ASC Topic 320, *Investments—Debt and Equity Securities*.

In February and March 2015, InexBio Holdings, LLC (Holdings), an entity owned 50% by Cambridge Equities, L.P., an entity in which the Company's CEO is the sole member of its general partner, and 50% Eragon Ventures, LLC, an entity of which one of the Company's former directors is managing member, acquired 220,000 shares or 67.3% of Inex Bio from third party owners for \$1.1 million.

On March 30, 2015, the Company entered into a Stock Purchase Agreement with Holdings and the third party owners, pursuant to which the Company acquired all the remaining outstanding shares of Inex Bio not previously held by the Company.

The Company paid to the other owners of Inex Bio cash of \$1.5 million and issued warrants to acquire 593,072 shares of the Company's Class A common stock at an exercise price of \$2.00 per share. The Company valued the warrants using the Black-Sholes option-pricing model with a stock price of \$10.72 per share as of March 30, 2015, an expected term of 0.04 years, and a volatility of 80%. This resulted in a total fair value of the warrants of \$5.2 million. In April 2015, the Company received \$1.2 million for the full exercise of the warrants.

The Company recorded the transaction as an asset purchase because Inex Bio was a shell corporation without any employees or other significant assets and did not meet the definition of a business under ASC Topic 805, *Business Combinations*.

The purchase price paid to acquire Inex Bio from the other owners is as follows (in thousands):

Consideration	Total
Cash paid by InexBio Holdings, LLC	\$ 1,100
Cash paid by Company	1,482
Fair value of warrants	5,170
Aggregate purchase price	<u>\$ 7,752</u>

The following table summarizes the assets acquired and liabilities assumed (in thousands):

Cash	\$ 763
Intangible assets—reacquired rights of Company technology*	8,636
Other assets	42
Investment in Inex Bio	(221)
Deferred tax liability	(1,467)
Accounts payable	(1)
Total assets acquired and liabilities assumed	<u>\$ 7,752</u>

\* Inclusive of \$1.5 million intangible asset related to deferred tax liability.

The license solely covers pending patent applications at this time. The Company will amortize the intangible assets over 4 years, which represents the period until the next action date of the pending patent application in the territory of the license issued to Inex Bio.

The Company paid Holdings cash of \$6.5 million and issued warrants to acquire 2,609,520 shares of the Company's Class A common stock at an exercise price of \$2.00 per share for its assistance in negotiating the acquisition of Inex Bio from the other owners. The Company valued the warrants using the Black-Sholes option-pricing model with a stock price of \$10.72 per share as of March 30, 2015, an expected term of 0.04 years, and a volatility of 80%. This resulted in a fair value of total warrants of \$22.7 million. In April 2015, the Company received \$5.2 million for the full exercise of the warrants.

The following summarizes the net consideration paid to Holdings (in thousands):

Consideration	Total
Cash	\$ 6,518
Fair value of warrants	22,747
Less cash paid to acquire shares in Inex Bio	(1,100)
Net consideration	<u>\$ 28,165</u>

The Company recorded compensation expense for the portion of the cash and warrants issued to Holdings that exceeded the fair value of the shares acquired consistent with ASC Topic 718. The Company recorded \$22.7 million of stock-based compensation and \$5.4 million of cash compensation to the Company's chief executive officer and the former director as a result of acquiring their interest in Inex Bio.

## 12. Income Taxes

The difference between the federal statutory tax rate of 34% and the Company's 0% tax rate is due to losses in jurisdictions that the Company cannot benefit.

Intraperiod tax allocation rules require the Company to allocate the provision for income taxes between continuing operations and other categories of earnings, such as other comprehensive income. In periods in which the Company has a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as other comprehensive income, the Company must allocate the tax provision to the other categories of earnings. The Company then records a related tax benefit in continuing operations. During the three months ended March 31, 2016, the Company recorded unrealized gains on its marketable securities in other comprehensive income, net of taxes. As a result, for the three months ended March 31, 2016 and 2015, respectively, the Company recorded a \$52,000 and \$0 tax benefit on the condensed consolidated statement of operations and \$0.3 million and \$0 in other comprehensive income.

The Company is operating in Korea. During the three months ended March 31, 2016 and 2015, the tax benefit related to Korea is \$0.1 million and \$0, respectively.

The Company currently files federal and state income tax returns in the United States and in Korea.

Income tax expense consists of U.S. federal, state, and Korean income taxes. To date, the Company has not been required to pay U.S. federal income taxes because of current and accumulated net operating losses.

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

### Forward-Looking Statements

The following discussion and analysis should be read together with our condensed consolidated financial statements and the notes to those statements included elsewhere in this Quarterly Report on Form 10-Q, or Form 10-Q. This Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act, that are based on our management's beliefs and assumptions and on information currently available to our management. The forward-looking statements are contained principally in the section entitled "Risk Factors" and this Management's Discussion and Analysis of Financial Condition and Results of Operations. Forward-looking statements include, but are not limited to:

- Our ability to successfully remediate the control deficiencies that gave rise to the material weaknesses in our internal control over financial reporting discussed in Part I, Item 4, "Controls and Procedures;"
- our ability to pioneer immunotherapy, implement precision cancer medicine and change the current paradigm of cancer care;
- our expectations regarding the potential benefits of our strategy and technology;
- our expectations regarding the operation of our product candidates and related benefits;
- our ability to utilize multiple modes to induce cell death;
- our beliefs regarding the benefits and perceived limitations of competing approaches, and the future of competing technologies and our industry;
- details regarding our strategic vision and planned product candidate pipeline;
- our beliefs regarding the success, cost and timing of our product candidate development activities and clinical trials;
- our expectations regarding our ability to utilize the Phase I aNK clinical trial data to support the development of all of our product candidates;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses, including any planned IND filings or pursuit of accelerated regulatory approval pathways or orphan drug status and breakthrough therapy designations;
- our ability to implement an integrated discovery ecosystem and the operation of that planned ecosystem, including being able to regularly add neoepitopes and subsequently formulate new product candidates;
- the ability and willingness of strategic collaborators, including certain affiliates of NantWorks and Sorrento, to share our vision and effectively work with us to achieve our goals;
- the ability and willingness of various third parties to engage in research and development activities involving our product candidates, and our ability to leverage those activities;
- our ability to attract additional third party collaborators;
- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding the patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- our ability to produce an "off-the-shelf" therapy;
- our beliefs regarding the potential manufacturing and distribution benefits associated with our product candidates, and our ability to scale up the production of our product candidates;
- our plans regarding our planned manufacturing facility and CMO engagement;
- the ability to obtain and maintain regulatory approval of any of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to commercialize any approved products;
- the rate and degree of market acceptance of any approved products;
- our ability to attract and retain key personnel;

- the accuracy of our estimates regarding our any future revenue as well as our future operating expenses, future revenue, capital requirements and needs for additional financing;
- our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidate and not infringe upon the intellectual property of others;
- regulatory developments in the United States and foreign countries;
- our expectations regarding the period during which we qualify as an emerging growth company under the JOBS Act; and
- our use of proceeds from our initial public offering and recent private placements.

*Forward-looking statements include statements that are not historical facts and can be identified by terms such as “anticipates,” “believes,” “could,” “seeks,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should,” “will,” “would,” or similar expressions and the negatives of those terms.*

*Forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements expressed or implied by the forward-looking statements. We discuss these risks in greater detail in Part II, Item 1A, “Risk Factors,” elsewhere in this Form 10-Q filed with the Securities and Exchange Commission, or SEC. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management’s beliefs and assumptions only as of the date of this Form 10-Q.*

*Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future. You should read this Form 10-Q completely and with the understanding that our actual future results may be materially different from what we expect.*

*This Form 10-Q contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Form 10-Q, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.*

*In this Form 10-Q, “the Company,” “we,” “us” and “our” refer to NantKwest, Inc. and its subsidiaries*

## **Overview**

We are a pioneering clinical-stage immunotherapy company focused on harnessing the power of the innate immune system by using the natural killer cell to treat cancer, infectious diseases and inflammatory diseases. Natural killer, or NK, cells are the body’s first line of defense due to their innate ability to rapidly seek and destroy abnormal cells, such as cancer or virally-infected cells, without prior exposure or activation by other support molecules required to activate adaptive immune cells such as T-cells.

We believe that our proprietary NK cell line, coupled with our planned integrated discovery ecosystem, positions us to implement precision cancer medicine by leveraging the advances that have evolved during the past decade and addressing newly discovered challenges of cancer. Cancer is only recently understood to be a complex of rare diseases, with hundreds of patient-specific, cancer-promoting mutated proteins, some known and many more unknown called neoepitopes. Identifying and targeting these mutated proteins is our strategy to overcome the challenges of cancer in the era of genomics, transcriptomics and immuno-oncology. We believe neoepitopes, which are newly discovered antigens selectively expressed on the cancer cells and not on the essential normal tissue, represent large untapped targeting opportunities for immune effector cells such as our activated NK cells.

*Multiple Modes of Tumor Cell Killing.* Our immuno-oncology NK platform has multiple modes to potentially induce cell death against the tumor or infected cell by: (1) direct killing by binding to stress ligands expressed by the diseased cell with the release of toxic granules directly into the tumor cell; (2) antibody mediated killing by binding to antibodies administered in combination and enhancing the cancer killing effect of the administered antibody, enabling targeted cell killing through antibody dependent cellular cytotoxicity, or ADCC; and (3) target activated killing by binding to known or newly discovered tumor-specific antigens expressed on the surface of tumor cells and inducing cell death by the release of toxic granules directly into the tumor cell and by the release of cytokines and chemokines that recruit additional innate and adaptive immune responses, including the recruitment of cytotoxic T-cells.

Our targeted therapeutic areas include: (1) cancer, focusing on bulky hematological cancers and solid tumors as well as cancer stem cells, (2) infectious diseases, including viral, fungal and bacterial infections, and (3) inflammatory diseases, ranging from rare inherited diseases to more prevalent autoimmune disorders.

*Our Integrated Discovery Ecosystem for Precision Medicine.* In order to effectively target newly discovered neopeptides, we plan to integrate the following ecosystem to help drive the development of genetically modified NK cells anticipated to be directed against these cancer-promoting mutated proteins: (1) a high-speed supercomputing infrastructure to help identify both known antigens on the surface of tumor cells and neopeptides in clinical patients suffering from cancer, in a timely manner and at large scale; (2) a next-generation genomic and transcriptomic sequencing infrastructure to identify the expression of the neopeptides on the surface of the tumor cell, GPS Cancer developed by our affiliate entity NantOmics; (3) delivering the neopeptide via an adenoviral vector developed by an affiliate entity to induce IgG1 in-vivo production and ADCC activity by our High Affinity NK Cell (haNK); (4) a diverse library of human antibodies from which to interrogate and extract an antibody matching the neopeptide; and (5) an aNK and haNK cell potentially capable of being produced as a scalable cell-based “off-the-shelf” therapy without the need for patient compatibility matching. We expect to regularly add newly discovered neopeptides from our discovery engine, and we believe the thousands of newly discovered antigens selectively expressed on the cancer cells and not on the essential normal tissue will provide us with the ability to create new and targeted libraries of antibodies to be potentially delivered as living drugs for metastatic cancer cells and cancer stem cells.

We retain exclusive worldwide rights to clinical and research data, intellectual property and know-how developed with our aNK cells, as well as what we believe is the only clinical grade master cell bank of aNK cells in existence.

Since our inception in 2002, we have devoted substantially all of our resources to the discovery and development of our product candidates, including conducting clinical trials, and funding general and administrative support for these operations. To date, we have generated minimal revenue from non-exclusive license agreements with numerous pharmaceutical and biotechnology companies granting the right to use our cell lines and intellectual property for non-clinical use. As described below, on June 9, 2015, we spun out these non-exclusive license agreements for non-clinical uses to Brink Biologics, Inc. (Brink Biologics) in exchange for all of the issued and outstanding shares of Brink Biologics, which were subsequently distributed by a dividend to our stockholders. We have not generated any revenue from product sales. We have incurred net losses in each year since our inception and, as of March 31, 2016, we had an accumulated deficit of approximately \$281.0 million. Our net losses were approximately \$236.9 million and \$6.2 million for the years ended December 31, 2015 and 2014, respectively, and approximately \$30.7 million and \$32.8 million for the three months ended March 31, 2016 and 2015, respectively. Substantially all of our net losses resulted from stock-based compensation expense and costs incurred in connection with our research and development programs and from selling, general and administrative costs associated with our operations.

As of March 31, 2016 we had 41 employees and currently, we have 44 employees. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, which may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- potentially seek regulatory approval for our product candidates;
- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates development and future commercialization efforts;

- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

We do not expect to generate any revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we do not expect to happen for at least the next several years, if ever. Until such time that we can generate substantial revenue from product sales, if ever, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all, which would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our research and development programs or commercialization efforts. Failure to receive additional funding could cause us to cease operations, in part or in full.

#### **Agreements with Affiliates of NantWorks**

Our Chairman and Chief Executive Officer, Dr. Soon-Shiong, founded and has a controlling interest in NantWorks, LLC (NantWorks), which is a collection of multiple companies in the healthcare and technology space. We have entered into arrangements with certain affiliates of NantWorks described below that, taken together, we expect will facilitate the development of new genetically modified NK cells for our product pipeline.

In March 2016, NantBioScience, Inc. (NantBioScience), a NantWorks company, and the National Cancer Institute entered into a cooperative research and development agreement. The agreement covers NantBioScience and its affiliates, including NantKwest. Under the agreement, we will collaborate on the preclinical and clinical development of proprietary recombinant NK cells and monoclonal antibodies in monotherapy and in combination immunotherapies. We expect to benefit from the preclinical and clinical research conducted during the first year under this agreement and are providing the first year of funding under the five-year agreement. In April 2016, we paid \$0.6 million to the National Cancer Institute as a prepayment for this first year of funding. We will recognize research and development expense ratably over a 12-month period.

In November 2015, we entered into a shared services agreement with NantWorks under which NantWorks will provide corporate, general and administrative, manufacturing strategy, regulatory and clinical trial strategy and other support services to us. We will be charged for the services at cost plus reasonable allocations for indirect costs that relate to the employees providing the services. For the three months ended March 31, 2016, we recorded \$0.8 million of selling, general and administrative expenses and \$0.3 million of research and development expenses on the condensed consolidated statement of operations under this arrangement.

In November 2015, we entered into a facility license agreement with NantWorks, effective in May 2015, for approximately 9,500 square feet of office space in Culver City, California, which is to be converted to a research and development laboratory and a Good Manufacturing Practices, or GMP, laboratory. The term of the license extends through December 2020. We have the option to extend the license through December 2023. The annual license fee is \$0.6 million with annual increases of three percent (3%) beginning in January 2017. Additional terms for the license shall be determined at fair market value. For the three months ended March 31, 2016, we recorded rent expense of \$0.1 million, included in research and development on the condensed consolidated statement of operations.

Under the facility license agreement with NantWorks, we are responsible for costs to build out the laboratory and have incurred costs of approximately \$3.2 million as of March 31, 2016, which are reflected as construction in progress. Additionally, in order for the facility to meet our research and development and GMP laboratory specifications, we have made structural changes as part of the conversion from office to laboratory space, and as a result, have concluded that we are “deemed owner” of the building (for accounting purposes only) during the construction period. Accordingly, we recorded a non-cash build-to-suit lease asset of \$2.7 million on the condensed consolidated balance sheet, representing our estimate of the fair market value of the building, and a corresponding construction build-to-suit lease liability.

In June 2015, we entered into an agreement with NantOmics, LLC, or NantOmics, to obtain genomic sequencing and proteomic analysis services, as well as related data management and bioinformatics services, exclusively from NantOmics. We will have rights to use the data and results generated from NantOmics’ services in connection with the performance of the particular oncology trial with respect to which the services were performed, but NantOmics will own the data and results, as well as any other intellectual property it creates in performing these services for us. We incurred \$0.1 million in costs for the three months ended March 31, 2016. We are obligated to pay NantOmics a fixed, per sample fee, determined based on the type of services being provided. The agreement has an initial term of five years and renews automatically for successive one year periods, unless terminated by us or NantOmics. We and NantOmics have the right to terminate the agreement for convenience on 90 days prior written notice, or in the event there is a material, uncured breach of the agreement by the other party.



In June 2015, we spun out Brink Biologics, Inc., or Brink Biologics, and Coneksis, Inc., or Coneksis. Our Chairman and Chief Executive Officer has a controlling interest in Brink Biologics and Coneksis. For a description of each of these transactions see the disclosure under “Spin-Out of Testing and Diagnostic Products and Services” and “Spin-Out of Veterinary Oncology Rights” below.

### **Spin-Out of Testing and Diagnostic Products and Services**

On June 9, 2015, we spun out our business relating to testing and diagnostic products and services to Brink Biologics in exchange for all of the issued and outstanding shares of Brink Biologics. We subsequently distributed the shares of Brink Biologics by a dividend to our stockholders of record on June 9, 2015, on a pro rata basis. Under the spin-out arrangement, we transferred to Brink Biologics all of our existing, revenue-earning, non-exclusive license agreements that allow third parties to use our cell lines and intellectual property for non-clinical laboratory testing, and also transferred or licensed to Brink Biologics our other assets pertaining to testing and diagnostics products and services. Our board of directors determined that our strategic focus is to utilize our resources to pursue the potential treatment of cancer, infectious diseases and inflammatory diseases, rather than to utilize our resources and intellectual property to focus on non-clinical laboratory testing for minimal revenue opportunities as compared to the potential market opportunity that may exist for our therapeutic focus. We granted to Brink Biologics worldwide, exclusive licenses, for use only in the field of in vitro and in vivo testing and diagnostic products and services and under certain cell lines, trademarks, know-how and patents, including the intellectual property rights licensed to us under our license agreement with Fox Chase Cancer Center. Brink Biologics is restricted in its ability to modify the licensed cell lines, and we will have at least joint ownership of any such modifications and the ability to use those modifications outside Brink Biologics’ field. We also have a non-exclusive license to any results and data arising from Brink Biologics’ use of our cell lines and intellectual property for our use for internal research purposes and outside of Brink Biologics’ field. In consideration for the license grants, Brink Biologics is obligated to pay us a low single-digit royalty on amounts received for the sale of licensed products and services, as well as a low single-digit percentage share of other revenue received by Brink Biologics from the grant of sublicenses under our rights. For the three months ended March 31, 2016, we recorded \$1,400 in revenue for royalties. Brink Biologics has the right to terminate the license agreement for convenience. We have the right to terminate the license agreement if Brink Biologics challenges any of our patents or the patents licensed to us by Fox Chase Cancer Center. We and Brink Biologics each have the right to terminate the license agreement if the other party is dissolved or is declared bankrupt, or remains in breach of any material obligation following a sixty day cure period to remedy the breach. Also, as part of the spin-out arrangement, we have agreed to provide certain services to Brink Biologics for a transitional period on a fee-for-service basis. As of three months ended March 31, 2016, we recorded \$7,000 for service fees from Brink Biologics, which is recorded in other income on our condensed consolidated statements of operations. We further determined that we have a variable interest in Brink Biologics through our royalty agreement with Brink Biologics. However, we are not the primary beneficiary, and as such, do not consolidate the entity.

### **Spin-Out of Veterinary Oncology Rights**

On June 9, 2015, we spun out our business relating to veterinary oncology to Coneksis in exchange for all of the issued and outstanding shares of Coneksis. We subsequently distributed the shares of Coneksis by a dividend to our stockholders of record on June 9, 2015, on a pro rata basis. In connection with the spin-out arrangement, we granted to Coneksis worldwide, exclusive licenses, for use only in the field of veterinary medical research and therapeutics, under certain cell lines, trademarks, know-how and patents, including the intellectual property rights licensed to us under our license agreement with Fox Chase Cancer Center. Like Brink Biologics, Coneksis is restricted in its ability to modify the licensed cell lines, and we will have at least joint ownership of any such modifications and the ability to use those modifications outside Coneksis’ field. We also have a non-exclusive license to any results and data arising from Coneksis’ use of our cell lines and intellectual property for our use for internal research purposes and outside of Coneksis’ field. In consideration for the license grants, Coneksis is obligated to pay us a low single-digit royalty on amounts received for the sale of licensed products and services, as well as a low single-digit percentage share of other revenue received by Coneksis from the grant of sublicenses under our rights. Coneksis has the right to terminate the license agreement for convenience. We have the right to terminate the license agreement if Coneksis challenges any of our patents or the patents licensed to us by Fox Chase Cancer Center. We and Coneksis each have the right to terminate the license agreement if the other party is dissolved or is declared bankrupt, or remains in breach of any material obligation following a sixty day cure period to remedy the breach. Finally, as part of the spin-out arrangement, we have agreed to provide certain services to Coneksis for a transitional period on a fee-for-service basis. For the three months ended March 31, 2016, we recorded \$1,500 for service fees from Coneksis, which is recorded in other income on our condensed consolidated statements of operations. We further determined that we have a variable interest in Coneksis through our royalty agreement with them. However, we are not the primary beneficiary, and as such, do not consolidate the entity.

## Inex Bio Acquisition

In April 2012, we made a strategic decision to enter into a License Agreement, or the Inex License Agreement, with Inex Bio, Inc. or Inex Bio, a Republic of Korea corporation. Under the Inex License Agreement, we provided Inex Bio with an exclusive license to our technology to be used in products only in certain Asian countries. In exchange for the exclusive license, we received a \$0.3 million up-front license fee. In addition, we were entitled to receive milestone payments of up to \$0.8 million based upon the completion of certain clinical trials and a 5% royalty on the net sales of applicable products using our aNK cells. No milestone payments or royalties have ever been due or received under this agreement.

In May 2012, we acquired 57,000 shares of Inex Bio for \$0.2 million, which represented 22.2% of the outstanding shares and 17.4% of the fully-diluted shares of Inex Bio. At that time, Inex Bio had only one other stockholder and one option holder.

In February 2015, following Dr. Soon-Shiong and Dr. Henry Ji, one of our former directors, joining us, we determined that reacquiring the rights licensed in certain Asian countries was of strategic importance to our future potential commercial strategy. Drs. Soon-Shiong and Ji helped facilitate our reacquisition of these rights through the acquisition of Inex Bio, using their relationships with the other Inex Bio stockholders. Drs. Soon-Shiong and Ji facilitated the acquisition through the formation of Inex Bio Holdings, LLC, or Inex Bio Holdings, which purchased shares of Inex Bio from third party stockholders. Cambridge Equities, LP, an entity of which Dr. Soon-Shiong is the sole member of its general partner, and Eragon Ventures, LLC, an entity of which Dr. Ji was the managing member, each owned fifty percent (50%) of InexBio Holdings.

In February and March 2015, InexBio Holdings paid \$1.1 million in cash to the third party stockholders to acquire a 67.3% interest in Inex Bio. Following this transaction, we owned a 22.2% interest in Inex Bio, InexBio Holdings owned a 67.3% interest in Inex Bio and the third party stockholders held the remainder of the Inex Bio shares. We believed that it was in our best interest for InexBio Holdings to acquire the shares directly from the third party stockholders of Inex Bio because of Dr. Soon-Shiong's and Dr. Ji's relationships with the stockholders and our belief that this would be the quickest manner to effect the acquisition and at the lowest price.

On March 30, 2015, we entered into a Stock Purchase Agreement with InexBio Holdings and certain other parties, or the purchase agreement, pursuant to which we acquired all the remaining outstanding shares of Inex Bio not previously owned by us for cash consideration of \$8.0 million and the issuance of a warrant to purchase 3,202,593 shares of our Class A common stock at an exercise price of \$2.00 per share. We paid (1) \$1.5 million in cash and warrants to purchase 593,072 shares of our Class A common stock valued at approximately \$5.2 million to the third party stockholders; and (2) \$6.5 million of cash and warrants to purchase 2,609,520 shares of our Class A common stock valued at \$22.7 million to Inex Bio Holdings. The purpose of providing the warrants was primarily to avoid having to use additional cash consideration for the acquisition. In addition, the subsequent exercise of the warrants by InexBio Holdings and other former shareholders of Inex Bio provided us with additional cash to fund our operations. At the time of our acquisition of the remaining shares of Inex Bio, Dr. Simon, our President and Chief Operating Officer, and one of our former directors, was on the board of directors of Inex Bio. Subsequent to the closing of the transaction, InexBio Holdings exercised the warrant we issued in connection with the transaction for 2,609,520 shares of our common stock for aggregate cash consideration to us of \$5.2 million.

During the second quarter of 2015, due to the price at which our common stock sold in a series of private placement transactions, we retroactively reassessed the estimated fair value per share of our common stock for financial reporting purposes. As a result of its reassessment, we determined that, solely for financial reporting purposes, the fair value of our common stock was higher than the fair market values determined in good faith by our board of directors for each of the option grant dates from and after January 2015. The exercise price of \$2.00 per share for the warrants issued to InexBio Holdings in March 2015 was based upon the fair market value determined in good faith by our board of directors. As a result of the retroactive reassessment in the second quarter of 2015, the issuance of the warrants resulted in compensation expense to Dr. Soon-Shiong and to Dr. Ji of \$22.7 million.

## Components of our Results of Operations

### Revenue

To date, we have derived substantially all of our revenue from non-exclusive license agreements with numerous pharmaceutical and biotechnology companies granting them the right to use our cell lines and intellectual property for non-clinical use. These agreements generally include upfront fees and annual research license fees for such use, as well as commercial license fees for sales of our licensee's products developed or manufactured using our intellectual property and cell lines. Our license agreements may also include milestone payments, although to date, we have not generated any revenue from milestone payments. We recognize revenue when there is persuasive evidence of an arrangement, delivery has occurred or we have provided the service, the fees are fixed and determinable and collectibility is reasonably assured. Our revenue from non-clinical license agreements decreased to a nominal amount as we have transferred virtually all of our revenue-generating license agreements to Brink Biologics in the spin-out transaction described above. In the future, we may generate revenue from license agreements entered into for therapeutic uses. To date, we have not generated any revenue from product sales. If we fail to complete the development of our product candidates in a timely manner or fail to obtain regulatory approval for them, we may never be able to generate substantial future revenue.

### Operating Expenses

We classify our operating expenses into research and development and selling, general and administrative expenses. Personnel costs including salaries, benefits, bonuses and specifically the stock-based compensation expense comprise a significant component of our research and development and selling, general and administrative expense categories. We allocate expenses associated with our facilities and information technology costs between these two categories based on the nature of each cost.

### Research and Development

Research and development expense consists of expenses incurred while performing research and development activities to discover and develop our product candidates. This includes conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for product candidates. We recognize research and development expenses as they are incurred. Our research and development expense primarily consists of:

- clinical trial and regulatory-related costs;
- expenses incurred under agreements with investigative sites and consultants that conduct our clinical trials;
- manufacturing and testing costs and related supplies and materials;
- employee-related expenses, including salaries, benefits, travel and stock-based compensation; and
- facility expenses dedicated to research and development.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs.

Substantially all of our research and development expenses to date have been incurred in connection with our product candidates. We expect our research and development expenses to increase significantly for the foreseeable future as we advance an increased number of our product candidates through clinical development, including the conduct of our planned clinical trials. The process of conducting clinical trials necessary to obtain regulatory approval is costly and time consuming. The successful development of product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of any product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates.

The costs of clinical trials may vary significantly over the life of a project owing to, but not limited to, the following:

- per patient trial costs;
- the number of sites included in the clinical trials;
- the countries in which the clinical trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the clinical trials;
- the number of doses that patients receive;

- the cost of comparative agents used in clinical trials;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidate.

We do not expect any of our product candidates to be commercially available for at least the next several years, if ever.

### **Selling, General and Administrative**

Selling, general and administrative expense consists primarily of salaries and personnel-related costs, including employee benefits and any stock-based compensation, for employees performing functions other than research and development. This includes personnel in executive, finance, human resources and administrative support functions. Other selling, general and administrative expenses include facility-related costs not otherwise allocated to research and development expense, professional fees for auditing, tax and legal services, advertising costs, expenses associated with obtaining and maintaining patents, consulting costs, royalties and licensing costs, and costs of our information systems.

Although our selling, general and administrative costs declined during the three months ended March 31, 2016 as compared to the three months ended March 31, 2015, we expect that our selling, general and administrative expenses will increase for the foreseeable future as we expand operations, internalize the manufacturing of our product candidates (including costs related to building out a state-of-the-art manufacturing facility as well as hiring additional employees to support our manufacturing and processing department), and operate as a public reporting company (including increased fees for outside consultants, lawyers and accountants, as well as increased directors' and officers' liability insurance premiums). We have incurred and expect that we will continue to incur in the future, additional costs associated with operating as a public company, including costs to comply with stock exchange listing and SEC requirements, corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public companies. Additionally, if and when we believe that regulatory approval of a particular product candidate appears likely, we expect to incur significant increases in our selling, general and administrative expenses relating to the sales and marketing of the approved product candidate.

### **Other Income (Expense)**

Other income (expense) consists primarily of income from our investments in marketable securities, non-cash costs related to fair value adjustments to our derivative warrant liability and foreign currency transaction expense.

In 2010, we issued, in conjunction with a termination and release agreement, a warrant to purchase 114,822 shares of Class A common stock. We accounted for the warrant as a derivative liability, which was adjusted to fair value each reporting period. The warrant was exercised in April 2015 and the derivative liability was reclassified to additional paid-in capital.

### **Income Tax**

Income tax expense consists of U.S. federal and state income taxes. To date, we have not been required to pay U.S. federal income taxes because of our current and accumulated net operating losses. Our income tax expense to date relates to income taxes in the States of California and Massachusetts. Our tax benefit relates to Korea and the Inex Bio acquisition.

## Results of Operations

### Comparison of the three months ended March 31, 2016 and 2015

	Three Months Ended March 31,		Period-to- Period Change
	2016	2015	
	(unaudited, in thousands)		
Revenue	\$ 6	\$ 120	\$ (114)
Operating expenses:			
Research and development	4,944	603	4,341
Selling, general and administrative	26,651	31,618	(4,967)
Total operating expenses	31,595	32,221	(626)
Loss from operations	(31,589)	(32,101)	512
Other income:			
Investment income, net	768	32	736
Change in fair value of warrant liability	—	(883)	883
Other income (expense), net	28	104	(76)
Total other income	796	(747)	1,543
Loss before income taxes	(30,793)	(32,848)	2,055
Income tax (benefit) expense	(143)	1	(144)
Net loss	\$ (30,650)	\$ (32,849)	\$ 2,199

### Revenue

Revenue decreased \$0.1 million during the three months ended March 31, 2016 as compared to the three months ended March 31, 2015. The decrease was primarily attributable to the transfer to Brink Biologics in June 2015 of the majority of our existing revenue-earning, non-exclusive license agreements that allow third parties to use our cell line and intellectual property for non-clinical laboratory testing.

### Research and Development

Research and development expense increased \$4.3 million during the three months ended March 31, 2016 as compared to the three months ended March 31, 2015. The increase was primarily attributable to a \$1.7 million increase in compensation expense related to increased staff and fees for services under our shared services agreement with NantWorks, \$1.5 million in laboratory and clinical trial expenses, \$0.6 million for new lab and manufacturing facility expense, and \$0.5 million for increased amortization on the technology license acquired on March 30, 2015 in connection with our acquisition of the remaining capital stock of Inex Bio. We expect our research and development expenses to increase significantly for the foreseeable future as we advance an increased number of our product candidates through clinical development and conduct our planned clinical trials.

### Selling, General and Administrative

Selling, general and administrative expense decreased \$5.0 million during the three months ended March 31, 2016 as compared to the three months ended March 31, 2015. The decrease was primarily attributable to a \$5.4 million decrease in personnel costs related to a cash consideration paid to our Chief Executive Officer, or CEO, and a former director in association with the acquisition of Inex Bio in 2015. The decrease was also attributable to a \$4.0 million decrease in stock compensation expense, of which \$22.7 million was related to the Inex Bio acquisition in 2015 and \$0.8 million was related to a retrospective reassessment, solely for financial reporting purposes, of estimated fair values of our common stock related to grants awarded in the first quarter of 2015, partially offset by increased stock compensation expense of \$19.5 million primarily related to equity awards granted to our CEO and President and Chief Operating Officer during 2015. These reductions were partially offset by increases of \$2.0 million in professional and consulting fees for accounting and compliance related services in connection with operating as a public company, \$1.6 million in compensation expense related to increased staff and shared services, \$0.4 million for a contribution made in 2016, and \$0.4 million for increased travel expenses.

### Other Income

Other income increased \$1.5 million during the three months ended March 31, 2016 as compared to the three months ended March 31, 2015. The increase was primarily attributable to a \$0.7 million increase in 2016 investment income related to our investments in marketable securities and a \$0.9 million reduction in the fair value of our 2015 derivative warrant liability.

## Liquidity and Capital Resources

### Sources of Liquidity

As of March 31, 2016, we had cash and cash equivalents of \$63.3 million, compared to \$175.9 million as of December 31, 2015. This change was primarily attributable to net cash used to purchase marketable securities of \$100.8 million and cash used in operating and financing activities of \$8.9 million and \$1.9 million, respectively.

Investments in marketable securities were \$274.7 million, of which \$158.5 million were short-term investments as of March 31, 2016 as compared to no marketable securities as of March 31, 2015.

*Stock Repurchase*—During the three months ended March 31, 2016, 300,000 shares were repurchased for \$2.6 million. There were no commissions as it was a private repurchase at the then current market price.

### Cash Flows

The following table sets forth our primary sources and uses of cash for periods indicated:

	Three Months Ended March 31,	
	2016	2015
	(unaudited, in thousands)	
Cash used in:		
Operating activities	\$ (8,856)	\$ (7,372)
Investing activities	(101,912)	(1,856)
Financing activities	(1,890)	(22)
Net decrease in cash and cash equivalents	<u>\$ (112,658)</u>	<u>\$ (9,250)</u>

### Operating Activities

For the three months ended March 31, 2016, our net cash used in operating activities of \$8.9 million consisted of a net loss of \$30.7 million, primarily attributable to \$20.5 million in stock compensation expense and \$10.2 million in research and development and selling, general and administrative expenses, partially offset by \$21.0 million in adjustments for non-cash items and \$0.8 million of cash provided by changes in working capital. Adjustments for non-cash items primarily consisted of the \$20.5 million in stock-based compensation expense, \$0.5 million in depreciation and amortization and \$0.4 million in amortization of premiums on marketable securities, reduced by \$0.3 million in non-cash interest and \$0.1 million of deferred income tax benefit. Changes in working capital consisted primarily of increases in accrued expenses of \$1.2 million, \$0.5 million of deferred rent, and due to related parties of \$0.3 million, partially offset by a decrease in accounts payable of \$0.7 million and an increase of \$0.5 million of other current and non-current assets.

For the three months ended March 31, 2015, our net cash used in operating activities of \$7.4 million consisted of a net loss of \$32.8 million, primarily attributable to a \$28.1 million compensation expense recorded for the portion of the cash and warrants issued to Inex Bio Holdings that exceeded the fair value of the Inex Bio, Inc. shares acquired as well as increases in spending on research and development efforts and selling, general and administrative expenses, partially offset by \$25.3 million in adjustments for non-cash items and \$0.1 million of cash provided in changes of working capital. Adjustments for non-cash items primarily consisted of \$24.5 million of stock-based compensation expense as a result of \$22.7 million in stock-based compensation to our Chief Executive Officer and a former director for their assistance in connection with the asset purchase of Inex Bio and a change in fair value of our derivative warrant liability of \$0.9 million.

### Investing Activities

For the three months ended March 31, 2016, net cash used in investing activities was \$101.9 million, which was primarily attributable to \$100.8 million in net purchases of marketable securities and \$1.1 million in purchases of property and equipment related to our laboratory and GMP build out in Culver City, California, and equipment purchases for the San Diego, California facility.

For the three months ended March 31, 2015, net cash used in investing activities was \$1.9 million, which was primarily attributable to the purchase of the remaining equity interest from unrelated third parties in Inex Bio, Inc.

## ***Financing Activities***

For the three months ended March 31, 2016, net cash used in financing activities was \$1.9 million, which consisted of \$2.6 million used for a stock repurchase offset by \$0.7 million in proceeds from the exercise of stock options and warrants.

For the three months ended March 31, 2015, net cash used in financing activities consisted of \$0.1 million in payments on notes payable partially offset by \$0.1 million in proceeds from the exercise of stock options.

## ***Future Funding Requirements***

To date, we have generated minimal revenue from non-exclusive license agreements with numerous pharmaceutical and biotechnology companies granting the right to use our cell lines and intellectual property for non-clinical use for laboratory testing that were spun out to Brink Biologics on June 9, 2015. We have not generated any revenue from product sales. We do not expect to generate significant revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates and we do not know when, or if, this will occur. In addition, we expect our expenses to significantly increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. Moreover, since the completion of our IPO in July 2015, we have incurred and expect that we will continue to incur in the future additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations. We expect that our expenses will increase substantially if and as we:

- continue research and development, including preclinical and clinical development of our existing product candidates;
- potentially seek regulatory approval for our product candidates;
- seek to discover and develop additional product candidates;
- establish a commercialization infrastructure and scale up our manufacturing and distribution capabilities to commercialize any of our product candidates for which we may obtain regulatory approval;
- seek to comply with regulatory standards and laws;
- maintain, leverage and expand our intellectual property portfolio;
- hire clinical, manufacturing, scientific and other personnel to support our product candidates development and future commercialization efforts;
- add operational, financial and management information systems and personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

Based upon our current operating plan, we expect that the net proceeds from our initial public offering and the concurrent private placement, together with our existing cash and cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. We have based this estimate on assumptions that may prove to be incorrect, and we may use our available capital resources sooner than we currently expect. The successful development of any product candidate is highly uncertain. Due to the numerous risks and uncertainties associated with the development and commercialization of our product candidates, if approved, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the development of our product candidates.

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

- the timing of, and the costs involved in, preclinical and clinical development and obtaining any regulatory approvals for our product candidates;
- the costs of manufacturing, distributing and processing our product candidates;
- the number and characteristics of any other product candidates we develop or acquire;
- our relative responsibility for developing and commercializing taNK product candidates covered by our joint development and license agreement with Sorrento Therapeutics;
- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements;
- the degree and rate of market acceptance of any approved products;

- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing intellectual property claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, any approved products; and
- any product liability or other lawsuits related to our product candidates.

Because all of our product candidates are in the early stages of preclinical and clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of any of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

### **Contractual Obligations, Commitments and Contingencies**

With the exception of entering into the lease agreements discussed below, during the three months ended March 31, 2016, there have been no material changes outside the ordinary course of business in our contractual obligations from those disclosed in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2015.

### **Leases**

In March 2016, we entered into a lease agreement for an approximately 7,893 square foot facility in Woburn, Massachusetts for a research and development laboratory, related office and other related uses. The lease has a four year term and the base rent is \$0.2 million per year with a \$1 per square foot annual increase on each anniversary date.

In March 2016, we extended the lease on the Cardiff-by-the-Sea, California office space until August 31, 2018. The current annual lease payment is \$0.1 million, and it will increase to \$0.2 million and \$0.2 million at September 1, 2016 and 2017, respectively.

### **Off-Balance Sheet Arrangements**

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Management’s discussion and analysis of our financial condition and results of operations are based upon our condensed consolidated financial statements which are prepared in accordance with GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to stock-based compensation, income taxes, preclinical and clinical trial accruals and build-to-suit lease asset. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.



With the exception of the preclinical and clinical trial accrual discussed below, there have been no significant changes to the items that we disclosed as our critical accounting policies in the Annual Report on Form 10-K for the year ended December 31, 2015.

### ***Preclinical and Clinical Trial Accruals***

As part of the process of preparing the financial statements, we are required to estimate expenses resulting from our obligations under contracts with vendors, clinical research organizations and consultants. The financial terms of these contracts vary and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

We estimate clinical trial and research agreement related expenses based on the services performed, pursuant to contracts with research institutions and clinical research organizations and other vendors that conduct clinical trials and research on our behalf. In accruing clinical and research related fees, we estimate the time period over which services will be performed and activity expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Payments made to third parties under these arrangements in advance of the receipt of the related services are recorded as prepaid expenses until the services are rendered.

### **Recent Accounting Pronouncements**

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update No. 2016-02, or ASU 2016-02, *Leases (Topic 842)*, which requires lessees to recognize assets and liabilities for operating leases with lease terms greater than twelve months in the balance sheet. The update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU 2016-02 on its consolidated financial statements and disclosures.

In March 2016, the FASB issued ASU 2016-09, *Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, as part of the initiative to reduce complexity in accounting standards. The areas for simplification in ASU 2016-09 involve several aspects of the accounting for employee share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities, or classification on the statement of cash flows. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of the adoption of ASU 2016-09 on its consolidated financial statements and disclosures.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.**

Financial market risks related to interest rates, foreign currency exchange rates and inflation are described in our 2015 Annual Report on Form 10-K. At March 31, 2016, there have been no material changes to the financial market risks described at December 31, 2015. We do not currently anticipate any other near-term changes in the nature of our financial market risk exposures or in management's objectives and strategies with respect to managing such exposures.

### **ITEM 4. CONTROLS AND PROCEDURES.**

#### ***Evaluation of Disclosure Controls and Procedures***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives of ensuring that information we are required to disclose in the reports we file or submit under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures, and is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. There is no assurance that our disclosure controls and procedures will operate effectively under all circumstances.

As disclosed in our 2015 Annual Report on Form 10-K in connection with our initial public offering, we concluded that there were material weaknesses in our internal control over financial reporting. Additionally, we disclosed on our Form 8-K filed on March 10, 2016 that our quarterly reports on Form 10-Q for the quarters ended June 30, 2015 and September 30, 2015 should no longer be relied upon due to the combined effect of financial statement errors primarily attributable to certain stock-based awards granted to the Company's Chairman and Chief Executive Officer and build-to-suit lease accounting related to one of our research and development and Good Manufacturing Practices or GMP facilities. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim condensed consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified relate to (1) our chief financial officer having almost complete responsibility for the processing of financial information; (2) our finance department not having adequate staff to process in a timely manner complex, non-routine transactions, including accounting for our investment in and asset purchase of Inex Bio, as well as transactions such as stock-based awards and build-to-suit leases; and (3) a lack of adequate staffing levels, resulting in insufficient time spent on review and approval of certain information used to prepare our condensed consolidated financial statements and the maintenance of effective controls to adequately monitor and review significant transactions for financial statement completeness and accuracy. These control deficiencies, although varying in severity, contributed to the material weaknesses in the control environment. If one or more material weaknesses persist or if we fail to establish and maintain effective internal control over financial reporting, our ability to accurately report our financial results could be adversely affected.

Because of the material weaknesses in our internal control over financial reporting as previously disclosed, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2015, our disclosure controls and procedures were not effective at the reasonable assurance level. Our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that notwithstanding the material weaknesses in our internal control over financial reporting, the condensed consolidated financial statements in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with U.S. GAAP.

#### ***Management's Remediation Efforts***

As we disclosed in our Annual Report on Form 10-K, we commenced measures to remediate the identified material weaknesses during the first quarter of 2015, including the identification of gaps in our skills base and expertise of the staff required to meet the financial reporting requirements of a public company. To address the issues, we have subsequently hired experienced personnel and have increased staffing levels by adding a Corporate Controller for oversight and review and financial consultants to assist in the accounting and financial reporting. We also plan to hire additional permanent accounting personnel.

We believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate these material weaknesses in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weaknesses in our internal control over financial reporting, which may necessitate additional implementation and evaluation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the known material weaknesses expeditiously.

#### ***Changes in Internal Control over Financial Reporting***

Other than described above, there were no changes in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### ***Inherent Limitations on Effectiveness of Controls***

Management recognizes that a control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or error, if any, have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

**ITEM 1. LEGAL PROCEEDINGS.**

From time to time, we may be involved in various other claims and legal proceedings relating to claims arising out of our operations. Except as noted below, 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.

***Securities Litigation***

In March 2016, a securities class action complaint was filed in federal district court in California against the Company related to the recently announced restatement of certain interim financial statements for the periods ending June 30, 2015 and September 30, 2015. The case, *Sudunagunta v. NantKwest, Inc., et al.*, is currently pending before the United States District Court for the Central District of California. The complaint names the Company and certain of its current and former officers and directors, as defendants. The complaint alleges that the defendants misrepresented material facts and/or mislead investors regarding the errors in our financial statements related to stock-based awards to our Chairman and Chief Executive Officer and build-to-suit lease accounting related to one of our research and development and good manufacturing practices facilities, and regarding the lack of effective internal financial controls. The complaint alleges violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. The complaint seeks unspecified damages, costs and attorneys' fees, and equitable/injunctive or other relief. Management intends to vigorously defend these proceedings. At this time, we cannot predict how the Court will rule on the merits of the claims and/or the scope of the potential loss in the event of an adverse outcome. Should we ultimately be found liable, our liability could have a material adverse effect on our results of operations for the period or periods in which it is incurred.

***Appeal of USPTO Decision***

In March 2009, we received a final rejection in one of our original patent applications pertaining to certain limited methods of use claims for NK-92 from the U.S. Patent and Trademark Office, or the USPTO (but the USPTO allowed claims on all of the other proposed claims, including other methods of use). We filed a Notice of Appeal to the USPTO Board of Appeals and Interferences, or the USPTO Board, and a Decision on Appeal was rendered in the fall of 2013. That decision reversed the Examiner's rejection of the claim to those certain limited methods of use. In December 2013, we brought an action in the U.S. District Court for the Eastern District of Virginia to review the decision of the USPTO as we disagreed with the decision as to the certain limited non-allowed claims. On September 2, 2015, the U.S. District Court granted the USPTO's motion for summary judgment. We are in the process of appealing the decision.

**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 other information included in our 2015 Annual Report on Form 10-K, including our financial statements and the related notes, and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," any of which may be relevant to decisions regarding an investment in or ownership of our stock. The occurrence of any of these risks could have a significant adverse effect on our reputation, business, financial condition, results of operations, growth and ability to accomplish our strategic objectives. We have organized the description of these risks into groupings in an effort to enhance readability, but many of the risks interrelate or could be grouped or ordered in other ways, so no special significance should be attributed to the groupings or order below.*

**Risks Related to Our Financial Condition and Capital Requirements**

***We are a clinical-stage biopharmaceutical company with a limited operating history and have incurred significant losses since our inception, and we anticipate that we will continue to incur losses for the foreseeable future, which makes it difficult to assess our future viability.***

We are a clinical-stage biopharmaceutical company with a limited operating history upon which our business can be evaluated. To date, we have generated minimal revenue from non-exclusive license agreements with biopharmaceutical companies to which we have granted the right to use our cell lines and intellectual property for non-clinical laboratory testing, and we have no products approved for commercial sale and have not generated any revenue from product sales. We have incurred operating losses on an annual basis since our formation and we may never become profitable. As of March 31, 2016, we had an accumulated deficit of approximately \$281.0 million. We incurred net losses of \$30.7 million and \$32.8 million for the three months ended March 31, 2016 and 2015, respectively. Our losses have resulted principally from costs incurred in ongoing preclinical studies, clinical trials and operations, research and development expenses, as well as general and administrative expenses.

A critical aspect of our strategy is to invest significantly in expanding our aNK platform and the development of our product candidates. We expect to incur significant expenses as we continue to expand our business, including in connection with conducting research and development across multiple therapeutic areas, participating in clinical trial activities, continuing to acquire or in-license technologies, maintaining, protecting and expanding our intellectual property, seeking regulatory approvals and, upon successful receipt of FDA approval, commercializing our products. We will also need to incur costs as we hire additional personnel and increase our manufacturing capabilities, including potentially pursuant to the lease or purchase of a facility, for the manufacturing of our product candidates for our planned clinical trials and, upon potential receipt of FDA approval, for our initial commercialization activities. Moreover, we do not expect to have any significant product sales or revenue for a number of years. These losses have had and, as our operating losses continue to increase significantly in the future due to these expenditures, will continue to have an adverse effect on our stockholders' equity and working capital. Because of the numerous risks and uncertainties associated with our product development efforts, we are unable to predict when we may become profitable, if at all. Additionally, our net losses may fluctuate significantly from quarter to quarter, and as a result a period to period comparison of our results of operations may not be meaningful.

***We do not have any therapeutic products that are approved for commercial sale. Our ability to generate revenue from product sales and achieve and maintain profitability depends significantly on our success in a number of factors.***

We currently do not have any therapeutic products that are approved for commercial sale. We have not received, and do not expect to receive for at least the next several years, if at all, any revenues from the commercialization of our product candidates if approved. To obtain revenues from sales of our product candidates that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing therapies with commercial potential. Our ability to generate revenue and achieve profitability depends significantly on our success in many areas, including:

- our research and development efforts, including preclinical studies and clinical trials of our aNK platform and our product candidates;
- developing sustainable, scalable, reliable and cost-effective manufacturing and distribution processes for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own current good manufacturing processes, or cGMPs, manufacturing facilities and processes;
- addressing any competing technological and industry developments;
- identifying, assessing, acquiring and/or developing new technology platforms and product candidates across numerous therapeutic areas;
- obtaining regulatory approvals and marketing authorizations for product candidates;
- launching and commercializing any approved products, either directly or with a collaborator or distributor;
- obtaining market acceptance of and acceptable reimbursement for any approved products;
- completing collaborations, licenses and other strategic transactions on favorable terms, if at all;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and we may not generate significant revenue from sales of such products, resulting in limited or no profitability in the future. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital for the foreseeable future. Any failure to become and remain profitable may adversely affect the market price of our common stock, our ability to raise capital and our future viability.

***We will need to obtain substantial additional financing to complete the development and any commercialization of our product candidates, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our commercialization efforts, product development or other operations.***

Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially in the foreseeable future. Developing our product candidates and conducting clinical trials for the treatment of cancer and other diseases will require substantial amounts of capital. We will also require a significant additional amount of capital to commercialize any approved products.

As of March 31, 2016, we had cash and cash equivalents of \$63.3 million and \$274.7 million of marketable securities. We are using and expect to continue to use the net proceeds from our initial public offering and the concurrent private placement to fund expenses in connection with our planned clinical trials, our planned manufacturing facility and processes and the hiring of additional personnel, and for other research and development activities, working capital and general corporate purposes. We believe that such proceeds, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least the next 24 months. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require additional capital for the further development and any commercialization of our product candidates and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

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

- the timing of, and the costs involved in, preclinical and clinical development and obtaining any regulatory approvals for our product candidates;
- the costs of manufacturing, distributing and processing our product candidates;
- the number and characteristics of any other product candidates we develop or acquire;
- our relative responsibility for developing and commercializing taNK product candidates covered by our joint development and license agreement with Sorrento Therapeutics;
- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements;
- the degree and rate of market acceptance of any approved products;
- the emergence, approval, availability, perceived advantages, relative cost, relative safety and relative efficacy of other products or treatments;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing intellectual property claims, including litigation costs and the outcome of such litigation;
- the timing, receipt and amount of sales of, or royalties on, any approved products; and
- any product liability or other lawsuits related to our product candidates.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or grant licenses on terms that may not be favorable to us. Additional capital may not be available when we need it, on terms that are acceptable to us or at all. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market any approved products that we would otherwise prefer to develop and market ourselves.

***We invest our cash on hand in various financial instruments which are subject to risks that could adversely affect our business, results of operations, liquidity and financial condition.***

We invest our cash in a variety of financial instruments, principally commercial paper, corporate debt securities and foreign government bonds. All of these investments are subject to credit, liquidity, market and interest rate risk. Such risks, including the failure or severe financial distress of the financial institutions that hold our cash, cash equivalents and investments, may result in a loss of liquidity, impairment to our investments, realization of substantial future losses, or a complete loss of the investments in the long-term, which may have a material adverse effect on our business, results of operations, liquidity and financial condition. In order to manage the risk to our investments, we maintain an investment policy that, among other things, limits the amount that we may invest in any one issue or any single issuer and requires us to only invest in high credit quality securities.

***The restatement of our interim financial statements for the quarters ended June 30, 2015 and September 30, 2015 may affect shareholder confidence, may consume a significant amount of our time and resources, and may have a material adverse effect on our business and stock price.***

As disclosed in our Current Report on Form 8-K filed with the SEC on March 10, 2016, we have restated our interim financial statements for the quarters ended June 30, 2015 and September 30, 2015. The restatements, which are included in our 2015 Annual Report, are attributable to certain stock-based awards to the Company's Chief Executive Officer and Chairman and build-to-suit lease accounting related to one of its research and development and Good Manufacturing Practices, or GMP, facilities. Specifically, errors resulted from the modification of the performance-based vesting criteria to a combination of performance-based and services-based vesting criteria of a warrant subsequent to the grant date and the value of non-cash, stock-based compensation expense recorded by the Company for the quarters ended June 30, 2015 and September 30, 2015. The error related to the use of build-to-suit lease accounting, which resulted from the Company's involvement in the construction of structural improvements to the leased facility space and, therefore, was deemed the owner, for accounting purposes, of the construction project having a non-cash impact for the quarters ending June 30, 2015 and September 30, 2015.

Although we plan to complete this remediation process as quickly as possible, we cannot at this time estimate how long it will take, and our measures may not prove to be successful in remediating these material weaknesses. If our remedial measures are insufficient to address the material weaknesses, or if additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our condensed consolidated financial statements may contain material misstatements and we could be required to further restate our financial results. In addition, if we are unable to successfully remediate the material weaknesses in our internal controls 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 applicable stock exchange listing requirements.

***We are involved in pending securities litigation and an adverse resolution of such litigation may adversely affect our business, financial condition, results of operations and cash flows.***

Following our announcement that we have restated our interim financial statements for the quarters ended June 30, 2015 and September 30, 2015 to address errors related to certain stock-based awards to the Company's Chairman and Chief Executive Officer and build-to-suit lease accounting related to one of our research and development and a Good Manufacturing Practices, or GMP, facilities, we became the subject of a lawsuit alleging securities law violations. This type of litigation can be expensive and disruptive to normal business operations, and the outcome can be difficult to predict regardless of the facts involved. An unfavorable outcome with respect to any of these lawsuits could have a material adverse effect on our business, financial condition, results of operations or cash flows. For additional information regarding this and other lawsuits in which we are involved, see Part II, Item 1, *Legal Proceedings*.

#### **Risks Relating to Our Business and Industry**

***The foundation of our business is based upon the success of our aNK cells as a technology platform. Our aNK platform and other product candidate families, including genetically modified taNK and haNK product candidates, will require significant additional clinical testing before we can potentially seek regulatory approval and launch commercial sales.***

Our business and future success depend on our ability to utilize our aNK cells as a technology platform, and to obtain regulatory approval of, and then successfully commercialize, our product candidates addressing numerous therapeutic areas. Our aNK platform and our product candidate families haNK and taNK are in the early stages of development and may never become commercialized. All of our product candidates developed from our technology platform will require additional clinical and non-clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. Because all of our product candidates are based on the same core aNK technology, if any of our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, these could impact the development plans for our other product candidates.

***Utilizing aNK cells represents a novel approach to immunotherapy, including cancer treatment, and we must overcome significant challenges in order to successfully develop, commercialize and manufacture our aNK and other product candidates.***

We have concentrated our research and development efforts on utilizing aNK cells as an immunotherapy platform and genetically modified aNK cells as product candidates based on this platform. We believe that our product candidates represent a novel approach to immunotherapy, including cancer treatment. Advancing this novel immunotherapy creates significant challenges for us, including:

- educating medical personnel regarding the potential side effect profile of our cells;
- enrolling sufficient numbers of patients in clinical trials;

- developing a reliable, safe and effective means of genetically modifying our cells;
- manufacturing our cells on a large scale and in a cost-effective manner;
- submitting applications for and obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with commercial development of immunotherapies for cancer; and
- establishing sales and marketing capabilities, as well as developing a manufacturing process and distribution network to support the commercialization of any approved products.

We must be able to overcome these challenges and others in order for us to successfully develop, commercialize and manufacture our product candidates utilizing aNK cells.

***Even if we successfully develop and commercialize our aNK product candidate for Merkel cell carcinoma, we may not be successful in developing and commercializing our other product candidates, and our commercial opportunities may be limited.***

While our most advanced product candidate is our aNK product candidate for Merkel cell carcinoma, we believe that our future success is highly dependent upon our ability to successfully develop and commercialize our other product candidates as well. We are simultaneously pursuing preclinical and clinical development of a number of product candidates spanning several therapeutic areas, including various types of cancer and infectious and inflammatory diseases. For example, we are devoting substantial resources toward the development of haNK product candidates, which we plan to develop as combination therapies with commercially approved mAbs and late-stage product candidates, and taNK product candidates, which we plan to develop for acute myeloid leukemia, or AML, bulky hematological cancers and solid tumors. In addition, our ability to realize the full value of our aNK platform will depend on our success in pursuing our other planned product candidates for a wide range of other indications.

Even if we are successful in continuing to build our pipeline of additional product candidates based on our technology platform, obtaining regulatory approvals and commercializing any approved product candidates will require substantial additional funding beyond the net proceeds of our initial public offering and are prone to numerous risks of failure. Investment in biopharmaceutical product development involves significant risks that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile to the satisfaction of regulatory authorities, gain regulatory approval or become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any product candidates through the development process. Our research programs may initially show promise in identifying additional product candidates, yet fail to yield additional product candidates for clinical development or commercialization for many reasons, including the following:

- our additional product candidates may not succeed in preclinical or clinical testing due to failing to generate enough data to support the initiation or continuation of clinical trials or due to lack of patient enrollment in clinical trials;
- a product candidate may be shown to have harmful side effects or other characteristics in larger scale clinical studies that indicate it is unlikely to meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates from our technology platform;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being manufactured in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

If any of these events occur, we may be forced to abandon our development efforts for a product candidate or the entire platform, or we may not be able to identify, discover, develop or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations.

***We may not be able to file INDs to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed in a timely manner, or at all.***

Prior to commencing clinical trials in the United States for any of our product candidates, we may be required to have an allowed IND for each product candidate. We currently have only one allowed IND for our aNK product candidate for Merkel cell carcinoma, and are required to file additional INDs prior to initiating our planned clinical trials. We believe that the data from previous preclinical studies will support the filing of additional INDs, to enable us to undertake additional clinical studies as we have planned. However, submission of an IND may not result in the FDA allowing further clinical trials to begin and, once begun, issues may arise that will require us to suspend or terminate such clinical trials. Additionally, even if relevant regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, these regulatory authorities may change their requirements in the future. The fact that we are pursuing novel technologies may also exacerbate these risks with respect to our product candidates, and as a result we may not meet our anticipated clinical development timelines.

***We face significant competition in the biopharmaceutical industry, and many of our competitors have substantially greater experience and resources than we have.***

Even if our aNK cell therapy proves successful, we might not be able to remain competitive because of the rapid pace of technological development in the biopharmaceutical field. Our aNK, haNK and taNK product candidates will compete with other cell-based immunotherapy approaches using T- and dendritic cells. We are aware of companies developing product candidates focused on NK cells. These companies include Bristol-Myers Squibb, Celgene Corporation and Innate Pharma. Companies that are currently focused on T-cell based treatments include Adaptimmune Limited, Amgen Inc., Bellicum Pharmaceuticals, Inc., bluebird bio, Inc., Celgene Corporation, Cellectis SA, GlaxoSmithKline plc, Intrexon Corporation, Juno Therapeutics, Inc., Kite Pharma, Inc., Novartis AG, Pfizer Inc. and Ziopharm Oncology, Inc. There is currently one approved dendritic cell-based cancer vaccine, PROVENGE, which is marketed by Valeant Pharmaceuticals for the treatment of metastatic castration-resistant prostate cancer. Other companies focused on developing dendritic cell-based product candidates include Argos Therapeutics, Inc., Biovest International, Inc., ImmunoCellular Therapeutics, Ltd., Immune Design, Inc., Inovio Pharmaceuticals, Inc., Intrexon Corporation and Northwest Biotherapeutics, Inc.

Many of our competitors have greater financial and other resources, larger research and development staffs, and more experienced capabilities in researching, developing and testing products than we do. All of these companies also have more experience in conducting clinical trials, obtaining FDA and other regulatory approvals, and manufacturing, marketing and distributing therapeutic products. Small companies like us may successfully compete by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. In addition, large pharmaceutical companies or other companies with greater resources or experience than us may choose to forgo therapy opportunities that would have otherwise been complementary to our product development and collaboration plans. Our competitors may succeed in developing, obtaining patent protection for, or commercializing their products more rapidly than us. A competing company developing or acquiring rights to a more effective therapeutic product for the same diseases targeted by us, or one that offers significantly lower costs of treatment, could render our products noncompetitive or obsolete.

***Our business plan involves the creation of a complex integrated ecosystem capable of addressing a wide range of indications. As a result, our future success depends on our ability to prioritize among many different opportunities.***

We do not have sufficient resources to pursue development of all or even a substantial portion of the potential opportunities that we believe will be afforded to us by our planned integrated ecosystem. Because we have limited resources and access to capital to fund our operations, our management must make significant prioritization decisions as to which product candidates to pursue, and how much of our resources to allocate to each. Our management has broad discretion to suspend, scale down, or discontinue any or all of these development efforts, or to initiate new programs to treat other diseases. If we select and commit resources to opportunities that we are unable to successfully develop, or we forego more promising opportunities, our business, financial condition and results of operations will be adversely affected.

***Our planned integrated ecosystem is to be comprised of multiple novel technologies that have never been tested in combination with our product candidates, and we do not know whether our attempts to use them in combination will be effective.***

Our business strategy includes using our integrated discovery engine to introduce new product candidates in combination with technologies that were developed by other companies with whom we have entered into strategic collaborations. Each technology and collaboration is unique and has its own risks, and the failure of any individual technology or the combination could materially impair our ability to successfully pursue our own aNK platform and related product candidates.



With respect to our agreement with Sorrento Therapeutics, Inc., or Sorrento, we have not yet jointly developed any taNK product candidates. Although Sorrento has one of the largest fully human antibody libraries in the world, Sorrento's antibodies may not be compatible with our taNK product candidates and there may be other libraries that would be more compatible with our technology and would produce better results for us. To the extent that we use antibodies from other parties for our taNK product candidates, we would still be required to pay royalties to Sorrento.

We have also entered into collaborations with affiliates of NantWorks to provide us with access to their database of genomic and proteomic information collected from a broad array of tumor cell samples. Our rights to use the database are non-exclusive and are governed by agreements cancelable with 90 days' notice, and we therefore cannot guarantee that we would ultimately have any competitive advantage based on our use of this technology. The database also may not be able to identify novel tumor-associated antigens that are targetable with our technology and the genetic and proteomic analysis capability may not be effective as a companion diagnostic to guide therapeutic treatments.

Although we have agreements with these parties, we cannot control their actions and they may make mistakes, work with our competitors, or not devote sufficient time and attention to us. The arrangements may become cost-prohibitive for us, and their technologies may become obsolete or better options may be available that we are unable to utilize. Using our technology in combination with theirs has never been tried, and we cannot assure you that we will be successful in producing product candidates in connection with these arrangements.

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, results of earlier studies and clinical trials may not be predictive of future clinical trial results, we may not be able to rely on the aNK Phase I clinical trial data for our other product candidates, and our clinical trials may fail to adequately demonstrate substantial evidence of safety and efficacy of our product candidates.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical trials can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. There is a high failure rate for drugs proceeding through clinical trials, and product candidates in later stages of clinical trials may fail to show the required safety and efficacy despite having progressed through preclinical studies and initial clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier clinical trials, and we cannot be certain that we will not face similar setbacks. Even if our clinical trials are completed, the results may not be sufficient to support obtaining regulatory approval for our product candidates. In addition, our strategy and anticipated timelines are predicated upon our ability to utilize the Phase I clinical trial data for aNK observed to date to support our planned clinical trials for all of our product candidates, including our haNK and taNK product candidates. To date, we have only one IND for our aNK product candidate, and we cannot assure you that the FDA will allow us to utilize the Phase I aNK data to support other planned clinical trials or allow our anticipated INDs for (1) planned Phase I or Phase I/II clinical trials for our other product candidates as potential monotherapies, (2) planned Phase II/III clinical trials for our haNK product candidates as potential combination therapies, or (3) any other planned clinical trials.

We have in the past experienced delays in our ongoing clinical trials and we may experience additional delays in the future. We do not know whether future clinical trials, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended or terminated by us, regulatory authorities, clinical trial investigators, and ethics committees for a variety of reasons, including failure to:

- generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials;
- obtain regulatory approval, or feedback on clinical trial design, to commence a clinical trial;
- identify, recruit and train suitable clinical investigators;
- reach agreement on acceptable terms with prospective CROs and clinical trial sites;
- obtain and maintain institutional review board, or IRB, approval at each clinical trial site;
- identify, recruit and enroll suitable patients to participate in a clinical trial;
- have a sufficient number of patients complete a clinical trial or return for post-treatment follow-up;
- ensure clinical investigators observe clinical trial protocol or continue to participate in a clinical trial;
- address any patient safety concerns that arise during the course of a clinical trial;
- address any conflicts with new or existing laws or regulations;

- add a sufficient number of clinical trial sites;
- timely manufacture sufficient quantities of product candidate for use in clinical trials; or
- raise sufficient capital to fund a clinical trial.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' or caregivers' perceptions as to the potential advantages of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such clinical trial or by the FDA or any other regulatory authority, or if the IRBs of the institutions in which such clinical trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements, including GCPs, or our clinical protocols, inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

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

***We may be unable to obtain regulatory approval for our product candidates. The denial or delay of any such approval would delay commercialization and have a material adverse effect on our potential to generate revenue, our business and our results of operations.***

The research, development, testing, manufacturing, labeling, packaging, approval, promotion, advertising, storage, recordkeeping, marketing, distribution, post-approval monitoring and reporting, and export and import of biopharmaceutical products are subject to extensive regulation by the FDA, and by foreign regulatory authorities in other countries. These regulations differ from country to country. To gain approval to market our product candidates, we must provide regulatory authorities with substantial evidence of safety, purity and potency of the product for each indication we seek to commercialize. We have not yet obtained regulatory approval to market any of our product candidates in the United States or any other country. Our business depends upon obtaining these regulatory approvals.

The FDA can delay, limit or deny approval of our product candidates for many reasons, including:

- our inability to satisfactorily demonstrate with substantial clinical evidence that the product candidates are safe, pure and potent for the requested indication;
- the FDA's disagreement with our clinical trial protocol or the interpretation of data from preclinical studies or clinical trials;
- the population studied in the clinical trial not being sufficiently broad or representative to assess safety in the full population for which we seek approval;
- our inability to demonstrate that clinical or other benefits of our product candidates outweigh any safety or other perceived risks;
- the FDA's determination that additional preclinical or clinical trials are required;
- the FDA's non-approval of the labeling or the specifications of our product candidates;
- the FDA's failure to accept the manufacturing processes or facilities of third-party manufacturers with which we contract; or
- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually successfully complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA may only grant approval contingent on the performance of costly additional post-approval clinical trials. The FDA may also approve our product candidates for a more limited indication or a narrower patient population than we originally requested, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our product candidates. To the extent we seek regulatory approval in foreign countries, we may face challenges similar to those described above with regulatory authorities in applicable jurisdictions. Any delay in obtaining, or our inability to obtain, applicable regulatory approval for any of our product candidates would delay or prevent commercialization of our product candidates and would materially adversely impact our business, results of operations, financial condition and prospects.

***Use of our product candidates could be associated with side effects or adverse events.***

As with most biopharmaceutical products, use of our product candidates could be associated with side effects or adverse events which can vary in severity and frequency. Side effects or adverse events associated with the use of our product candidates may be observed at any time, including in clinical trials or once a product is commercialized, and any such side effects or adverse events may negatively affect our ability to obtain regulatory approval or market our product candidates. Side effects such as toxicity or other safety issues associated with the use of our product candidates could require us to perform additional studies or halt development or sale of these product candidates or expose us to product liability lawsuits which will harm our business. We may be required by regulatory agencies to conduct additional preclinical or clinical trials regarding the safety and efficacy of our product candidates which we have not planned or anticipated. We cannot assure you that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or any regulatory agency in a timely manner or ever, which could harm our business, prospects and financial condition.

In the Phase I clinical trial of anNK conducted by Rush University, one case of transient grade 4 hypoglycemia and several mild-to-moderate fevers were seen in five out of six patients receiving higher doses. In the Phase I clinical trial of aNK conducted by the University of Frankfurt, one report of mild fever and a report of sustained back pain were observed. If we are successful in commercializing our product candidates, the FDA and other foreign regulatory agency regulations will require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may inadvertently fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA or other foreign regulatory agencies could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products.

***The clinical and commercial utility of our aNK platform is uncertain and may never be realized.***

Our aNK platform is in the early stages of development. aNK cells have only been evaluated in four Phase I clinical safety trials to date, in over 40 patients. These clinical trials were designed to evaluate safety and tolerability, and not designed to produce statistically significant results as to efficacy. Most of the data to date regarding aNK cells were derived from clinical trials not conducted by us, including physician-sponsored clinical trials, and utilizing product not manufactured by us but which we believe is comparable to aNK. Success in early clinical trials does not ensure that large-scale clinical trials will be successful nor does it predict final results. In addition, we will not be able to treat patients if we cannot manufacture a sufficient quantity of aNK cells that meet our minimum specifications. In addition, our haNK and taNK product candidates have never been tested in humans, and the results from the aNK clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of haNK and taNK.

We may not ultimately be able to provide the FDA with substantial clinical evidence to support a claim of safety, purity and potency sufficient to enable the FDA to approve aNK cells for any indication. This may be because later clinical trials fail to reproduce favorable data obtained in earlier clinical trials, because the FDA disagrees with how we interpret the data from these clinical trials, or because the FDA does not accept these therapeutic effects as valid endpoints in pivotal clinical trials necessary for market approval. We will also need to demonstrate that aNK cells are safe. We do not have data on possible harmful long-term effects of aNK cells and do not expect to have this data in the near future. As a result, our ability to generate clinical safety and effectiveness data sufficient to support submission of a marketing application or commercialization of our aNK cell therapy is uncertain and is subject to significant risk.

***We have limited experience as a company conducting clinical trials and rely on third parties to conduct many of our preclinical studies and clinical trials. Any failure by a third party or by us to conduct the clinical trials according to Good Clinical Practices, or GCPs, and in a timely manner may delay or prevent our ability to seek or obtain regulatory approval for or commercialize our product candidates.***

To date, only two clinical trials related to our product candidates have been conducted by us. All other clinical trials to date have been investigator-initiated studies sponsored by the investigator's institution. This lack of experience may contribute to our planned clinical trials not beginning or completing on time, if at all. Large-scale clinical trials will require significant additional resources and reliance on contract research organizations, or CROs, clinical investigators, or consultants. Consequently, our reliance on outside parties may introduce delays beyond our control. Our CROs and other third parties must communicate and coordinate with one another in order for our trials to be successful. Additionally, our CROs and other third parties may also have relationships with other commercial entities, some of which may compete with us. If our CROs or other third parties conducting our clinical trials do not perform their contractual duties or regulatory obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical trial protocols, GCPs, or other regulatory requirements or for any other reason, we may need to conduct additional clinical trials or enter into new arrangements with alternative CROs, clinical investigators or other third parties. We may be unable to enter into arrangements with alternative CROs on commercially reasonable terms, or at all.

We and the third parties upon which we rely are required to comply with GCPs. GCPs are regulations and guidelines enforced by regulatory authorities around the world, through periodic inspections, for products in clinical development. If we or these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and have to be repeated, and our submission of marketing applications may be delayed or the regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We are subject to the risk that, upon inspection, a regulatory authority will determine that any of our clinical trials fail to comply or failed to comply with applicable GCP regulations. In addition, our clinical trials must be conducted with material produced under current cGMP and Good Tissue Practice, or GTP, regulations, which are enforced by regulatory authorities. In addition, our clinical trials must be conducted with material produced under cGMP regulations, which are enforced by regulatory authorities. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

We also anticipate that part of our strategy for pursuing the wide range of indications potentially addressed by our aNK platform will involve further investigator-initiated clinical trials. While these trials generally provide us with valuable clinical data that can inform our future development strategy in a cost-efficient manner, we generally have less control over not only the conduct but also the design of these clinical trials. Third-party investigators may design clinical trials involving our product candidates with clinical endpoints that are more difficult to achieve or in other ways that increase the risk of negative clinical trial results compared to clinical trials we may design on our own. Negative results in investigator-initiated clinical trials, regardless of how the clinical trial was designed or conducted, could have a material adverse effect on our prospects and the perception of our product candidates.

***Our successful development of our taNK product candidates is heavily dependent upon our collaboration with Sorrento.***

In December 2014, we entered into a joint development and license agreement with Sorrento, pursuant to which the parties agreed to exclusively collaborate on research, development and commercialization of our taNK product candidates as may be agreed between the parties. The prospects for the product candidates depend on the expertise, development and commercial skills, and financial strength of Sorrento. Our collaboration with Sorrento may not be successful, and we may not realize the expected benefits from this collaboration, due to a number of important factors, including the following:

- Sorrento's technology platform or Sorrento itself could be slow, adversely affecting our ability to develop product candidates as quickly as we would otherwise be able to;
- whether we can successfully resolve disagreements related to which party should advance a particular program;
- in the event Sorrento advances a particular program, Sorrento will have sole control over development, spending, commercialization, and out-licensing;
- the continued service of certain key employees of Sorrento that we are dependent upon;
- the timing and amount of any payments we may receive under these agreements will depend on, among other things, the efforts, allocation of resources, and successful commercialization of the relevant product candidates by Sorrento and us; and
- Sorrento may change the focus of their development or commercialization efforts or pursue or emphasize higher-priority programs, including as a result of a change in control of Sorrento.

A failure of Sorrento to successfully develop our product candidates that are covered by the collaboration, or commercialize such product candidates, or the termination of our agreement with Sorrento may have a material adverse effect on our business, results of operations and financial condition. As of the date hereof, the parties have not yet agreed upon any projects under the joint development and license agreement; therefore Sorrento has no rights to use our NK cells or other technologies or intellectual property rights or to begin related research, development or commercialization activities and we are free to pursue, and are actively pursuing, research, development and commercialization activities with antibodies that may bind to various targets, including PDL1, ROR-1, CD33 and CD123.

***We are heavily dependent on our senior management, particularly Drs. Patrick Soon-Shiong and Barry Simon, and a loss of a member of our senior management team in the future could harm our business.***

If we lose members of our senior management, we may not be able to find appropriate replacements on a timely basis, and our business could be adversely affected. Our existing operations and continued future development depend to a significant extent upon the performance and active participation of certain key individuals, including Drs. Patrick Soon-Shiong, our Chairman and Chief Executive Officer and our principal stockholder, and Barry Simon, our President and Chief Operating Officer. Although Dr. Soon-Shiong will primarily focus on NantKwest matters and is highly active in our management, he does devote a certain amount of his time to a number of different endeavors and companies, including NantWorks, a collection of multiple companies in the healthcare and technology space, which he founded in 2011. Additionally, we are dependent on commercial relationships with various other parties affiliated with NantWorks and with Dr. Soon-Shiong, and we may enter into additional relationships in the future, including with respect to using an adenoviral vector developed by an affiliate entity, and if Dr. Soon-Shiong was to cease his affiliation with us or with NantWorks, these entities may be unwilling to continue these relationships with us on commercially reasonable terms, or at all. The risks related to our dependence upon Dr. Soon-Shiong are particularly acute given his ownership percentage, relationships, role in our company and reputation. If we were to lose Drs. Soon-Shiong or Simon, we may not be able to find appropriate replacements on a timely basis and our financial condition and results of operations could be materially adversely affected.

To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options and warrants that vest over time. Additionally, we provided warrants that vest upon the achievement of certain performance milestones to Dr. Soon-Shiong. The value to employees of stock options and warrants 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. We face significant competition for employees, particularly scientific personnel, from other biopharmaceutical companies, which include both publicly-traded and privately-held companies, and we may not be able to hire new employees quickly enough to meet our needs. 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. Except with respect to Dr. Simon, we do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

***Dr. Soon-Shiong, our Chairman and Chief Executive Officer and our principal stockholder, has significant interests in other companies which may conflict with our interests.***

Our Chairman and Chief Executive Officer, Dr. Soon-Shiong, is the founder of NantWorks and a large stockholder in Sorrento Therapeutics. Both Sorrento Therapeutics and the various NantWorks companies are currently exploring opportunities in the immunotherapy, infectious disease and inflammatory disease fields. As a result, they or other companies affiliated with Dr. Soon-Shiong may compete with us for business opportunities or, in the future, develop products that are competitive with ours (including products in the other therapeutic fields in which we may target in the future). As a result Dr. Soon-Shiong’s interests may not be aligned with our other stockholders and he may from time to time be incentivized to take certain actions that benefit his other interests and that our other stockholders do not view as being in their interest as investors in our company. Moreover, even if they do not directly relate to us, actions taken by Dr. Soon-Shiong and the companies with which he is involved could impact us. Given we changed our corporate name to NantKwest during 2015, this is particularly true of the various NantWorks companies.

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

To effect our business plan, we will need to rapidly add other management, accounting, regulatory, manufacturing and scientific staff. As of March 31, 2016, we only had 41 employees. We will need to attract, retain and motivate a significant number of new additional managerial, operational, sales, marketing, financial, and other personnel, as well as highly skilled scientific and medical personnel, and to expand our capabilities to successfully pursue our research, development, manufacturing and commercialization efforts and secure collaborations to market and distribute our products. This growth may strain our existing managerial, operational, financial and other resources. We also intend to add personnel in our research and development and manufacturing departments as we expand our clinical trial and research capabilities. Moreover, we will need to hire additional accounting and other personnel and augment our infrastructure as we transition to operating as a public company. Any inability to attract and retain qualified employees to enable our planned growth and establish additional capabilities or our failure to manage our growth effectively could delay or curtail our product development and commercialization efforts and harm our business.

***We have limited manufacturing experience and may not be able to manufacture aNK cells on a large scale or in a cost-effective manner.***

aNK cells have been grown in various quantities in closed-bag cell culture systems and smaller quantities in bioreactors. We or our third-party contractors will need to develop the ability to grow aNK cells on a large scale basis in a cost efficient manner. We have not demonstrated the ability to manufacture aNK cells beyond quantities sufficient for research and development and limited clinical activities. We have no experience manufacturing aNK cells specifically at the capacity that will be necessary to support large clinical trials or commercial sales, and have limited experience producing haNK and taNK cells, which may involve a more complex process(es) than manufacturing aNK cells. The novel nature of our technology also increases the complexity and risk in the manufacturing process. We are in the process of locating a site for the manufacture of aNK cells for our planned clinical trials and, if we receive FDA approval, initial commercialization. However, we may encounter difficulties in obtaining the approvals for, and designing, constructing, validating and operating, any new manufacturing facility. We may also be unable to hire the qualified personnel that we will require to accommodate the expansion of our operations and manufacturing capabilities. If we relocate our manufacturing activities to a new facility during or after a pivotal clinical trial, we may be unable to obtain regulatory approval unless and until we demonstrate to the FDA's satisfaction the similarity of our aNK cells manufactured in the new facility to our aNK cells manufactured in prior facilities. If we cannot adequately demonstrate similarity to the FDA, we could be required to repeat clinical trials, which would be expensive, and would substantially delay regulatory approval.

Because our product candidates are cell-based, their manufacture is complicated. In addition, we rely on certain third party suppliers for manufacturing supplies such as X-VIVO 10 media formulation to grow and produce the cells. Our present production process may not meet our initial expectations as to reproducibility, yield, purity or other measurements of performance. In addition, we may have to customize a bioreactor system to our manufacturing process. Because our manufacturing process is unproven, we may never successfully commercialize our products. In addition, because the clinical trials were conducted using a system that will not be sufficient for commercial quantities, we may have to show comparability of the different versions of systems we have used. For these and other reasons, we may not be able to manufacture aNK cells on a large scale or in a cost-effective manner.

aNK cells have been produced at academic institutions associated with our other clinical trial sites. In the past, the lack of production of aNK cells has caused delays in the commencement of our clinical trials. The Baylor Center for Cellular and Gene Therapy is currently producing aNK cells for our clinical trials at various clinical sites. We are adding NK cell production capacity in 2016 to meet anticipated demand for additional clinical trials but may not be able to successfully build at our capacity to meet our current and anticipated future needs. Any damage to or destruction of the Baylor Center facility or equipment, or our facility and equipment, when we secure it, prolonged power outage, contamination or shut down by the FDA or other regulatory authority could significantly impair or curtail our ability to obtain and produce aNK cells. In addition, the aNK cells of our master cell bank are stored in freezers at a third party biorepository (BioReliance), and aNK cells of our working cell bank are stored in freezers at the Baylor Center and BioReliance facilities, and will also be stored in our freezers when we establish production facilities. If these cells are damaged at both facilities, including by the loss or malfunction of these freezers or our back-up power systems, we would need to establish a replacement aNK master cell bank, which would delay our patients' treatments. If we are unable to establish a replacement aNK master cell bank, we could incur significant additional expenses and liability to patients whose treatment is delayed, and our business could suffer.

***If we or any of our third party manufacturers do not maintain high standards of manufacturing, our ability to develop and commercialize aNK cells could be delayed or curtailed.***

We and any third parties that we may use in the future to manufacture our products must continuously adhere to cGMP regulations rigorously enforced by the FDA through its facilities inspection program. If our facilities or the facilities of third parties who produce our products do not pass a pre-approval inspection, the FDA will not grant market approval for aNK cells. In complying with cGMP, we and any third-party manufacturers must expend significant time, money and effort in production, record-keeping and quality control to assure that each component of our aNK cell therapy meets applicable specifications and other requirements. We or any of these third-party manufacturers may also be subject to comparable or more stringent regulations of foreign regulatory authorities. If we or any of our third-party manufacturers fail to comply with these requirements, we may be subject to regulatory action, which could delay or curtail our ability to develop, obtain regulatory approval of, and commercialize aNK cells. If our component part manufacturers and suppliers fail to provide components of sufficient quality, and that meet our required specifications, our clinical trials or commercialization of aNK cells could be delayed or halted, and we could face product liability claims.

***If we or 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 us and any third-party manufacturers. We and 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 procedures for using, 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.

***We have not yet developed a validated methodology for freezing and thawing large quantities of aNK cells, which we believe will be required for the storage and distribution of our product candidates.***

We have not demonstrated that aNK cells can be frozen and thawed in large quantities without damage, in a cost-efficient manner and without degradation over time. We may encounter difficulties not only in developing freezing and thawing methodologies, but also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen product to the satisfaction of the FDA, we could be required to repeat clinical trials, which would be expensive and substantially delay regulatory approval. If we are unable to freeze aNK cells for shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing our production facility, will be limited. Even if we are able to successfully freeze and thaw aNK cells in large quantities, we will still need to develop a cost-effective and reliable distribution and logistics network, which we may be unable to accomplish. For these and other reasons, we may not be able to commercialize aNK cells on a large scale or in a cost-effective manner.

***We will rely on third party healthcare professionals to administer aNK cells to patients, and our business could be harmed if these third parties administer aNK cells incorrectly.***

We will rely on the expertise of physicians, nurses and other associated medical personnel to administer aNK cells to clinical trial patients. If these medical personnel are not properly trained to administer, or do not properly administer, aNK cells, the therapeutic effect of aNK cells may be diminished or the patient may suffer injury.

In addition, if we achieve the ability to freeze and thaw our aNK cells, third-party medical personnel will have to be trained on proper methodology for thawing aNK cells received from us. If this thawing is not performed correctly, the cells may become damaged and/or the patient may suffer injury. While we envision providing training materials and other resources to these third-party medical personnel, the thawing of aNK cells will occur outside our supervision and may not be administered properly. If, due to a third-party error, people believe that aNK cells are ineffective or harmful, the desire to use aNK cells may decline, which would negatively impact our business, reputation and prospects. We may also face significant liability even though we may not be responsible for the actions of these third parties.

***Even if any of our product candidates receive regulatory approvals, they may fail to achieve the broad degree of market acceptance and use necessary for commercial success.***

Any potential future commercial success of any of our product candidates will depend, among other things, on its acceptance by physicians, patients, healthcare payors, and other members of the medical community as a therapeutic and cost-effective alternative to commercially available products. Because only a few cell-based therapy products have been commercialized, we do not know to what extent cell-based immunotherapy products will be accepted as therapeutic alternatives. If we fail to gain market acceptance, we may not be able to earn sufficient revenues to continue our business. Market acceptance of, and demand for, any product that we may develop will depend on many factors, including:

- our ability to provide substantial evidence of safety and efficacy;
- convenience and ease of administration;
- prevalence and severity of adverse side effects;
- availability of alternative and competing treatments;
- cost effectiveness;
- effectiveness of our marketing and distribution strategy and pricing of any product that we may develop;
- publicity concerning our products or competitive products; and
- our ability to obtain sufficient third-party coverage and adequate reimbursement.

If aNK cells are approved for use but fail to achieve the broad degree of market acceptance necessary for commercial success, our operating results and financial condition will be adversely affected. In addition, even if aNK cells gain acceptance, the markets for treatment of patients with our target indications may not be as significant as we estimate.

***There are risks inherent in our business that may subject us to potential product liability suits and other claims, which may require us to engage in expensive and time-consuming litigation or pay substantial damages and may harm our reputation and reduce the demand for our product.***

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

Certain aspects of how aNK cells are processed and administered may increase our exposure to liability. Medical personnel administer aNK cells to patients intravenously in an outpatient procedure. This procedure poses risks to the patient similar to those occurring with infusions of other cell products, such as T cells and stem cells, including blood clots, infection and mild to severe allergic reactions. Additionally, aNK cells or components of our aNK cell therapy may cause unforeseen harmful side effects. For example, a patient receiving aNK cells could have a severe allergic reaction or could develop an autoimmune condition to materials infused with the aNK cells.

In addition, we have not conducted studies on the long-term effects associated with the media that we use to grow our aNK cells. Similarly, we expect to use media in freezing our aNK cells for shipment. These media could contain substances that have proved harmful if used in certain quantities. As we continue to develop our aNK cell therapy, we may encounter harmful side effects that we did not previously observe in our prior studies and clinical trials. Additionally, the discovery of unforeseen side effects of aNK cells could also lead to lawsuits against us.

Regardless of merit or eventual outcome, product liability or other claims may, among other things, result in:

- decreased demand for any approved products;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;



- a diversion of management's time and our resources;
- substantial monetary awards to clinical trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- loss of revenue; and
- the inability to commercialize any products we develop.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of our products. We are in the process of obtaining product liability insurance covering our clinical trials with policy limits that we believe are customary for similarly situated companies and adequate to provide us with coverage for foreseeable risks. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. If we determine that it is prudent to increase our product liability coverage due to the commercial launch of any approved product, we may be unable to obtain such increased coverage on acceptable terms, or at all. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing our product candidates, we intend to expand our insurance coverage to include the sale of the applicable products; however, we may be unable to obtain this liability insurance on commercially reasonable terms. If a successful product liability or other claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover these claims and our business operations could suffer.

***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 as a company in marketing products. If we develop internal sales, marketing and distribution organization, this would require significant capital expenditures, management resources and time, and we would have to compete with other pharmaceutical and biotechnology 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 expect to pursue collaborative arrangements regarding the sales, marketing and distribution of our products. However, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, their sales forces may not be successful in marketing our products. Any revenue we receive would depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the sales, marketing and distribution 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, marketing and distribution efforts of our product candidates. There can be no assurance that we will be able to develop internal sales, marketing distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the United States or overseas.

***A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business.***

We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations.

***We have formed, and may in the future form or seek, strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.***

We have formed, and may in the future form or seek, strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements 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 develop.

Any of these 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. 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 they 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. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

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

Our business model involves the storage and transmission of clinical trial and other data on our systems and on the systems of our consultants and contractors, and security breaches expose us to a risk of loss of this information, governmental fines and penalties, litigation and/or potential liability, in addition to negative publicity. Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. Our security measures and those of our contractors and consultants may also be breached due to employee error, malfeasance or otherwise. 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 clinical trial data from completed or future 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 third parties for research and development of our product candidates and to conduct clinical trials and may rely on third parties for the manufacture of our product candidates 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.

***Future acquisitions and investments could disrupt our business and harm our financial condition and operating results.***

Our success may depend, in part, on our ability to expand our products and services. In some circumstances, we may determine to do so through the acquisition of complementary businesses and technologies rather than through internal development. The identification of suitable acquisition candidates can be difficult, time-consuming and costly, and we may not be able to successfully complete identified acquisitions. The risks we face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- retention of key employees from the acquired company;
- coordination of research and development functions;
- integration of the acquired company's accounting, management information, human resources and other administrative systems;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, employee disputes, and alleged violations of laws; and
- unanticipated write-offs or charges.

Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally. Future acquisitions could also result in dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities, amortization expenses, incremental operating expenses or the write-off of goodwill, any of which could harm our financial condition or operating results.

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

Our operations, and those of our contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, acts of terrorism, acts of war 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 clinical 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 California near major earthquake faults and fire zones. Our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, clinical investigators, CROs, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to:

- comply with the laws of the FDA and other similar foreign regulatory bodies;
- provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies;
- comply with manufacturing standards we have established;
- comply with healthcare fraud and abuse, privacy and security and other laws in the United States and similar foreign fraudulent misconduct laws;
- comply with federal securities laws regulating insider trading; or
- report financial information or data accurately or to disclose unauthorized activities to us.

If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed 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, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also include the collection and/or use of information obtained in the course of patient recruitment for clinical trials. The healthcare laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or providing any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the civil False Claims Act, which impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from the federal government including Medicare and Medicaid, that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements, including mandatory contractual terms, on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, created under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, which we refer to collectively as ACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services, or HHS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members by the 90th day of each subsequent calendar year, and disclosure of such information will be made by HHS on a publicly available website; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we are subject to state and foreign laws and regulations that are analogous to the healthcare laws and regulations described above, among others, some of which may be broader in scope and may apply regardless of the payor. Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and relevant compliance guidance promulgated by the federal government; some state laws require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and some state and foreign laws govern the privacy and security of health information in ways that differ, and in certain cases are more stringent than, HIPAA, thus complicating compliance efforts.

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 do 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/or 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. Defending against any such actions can be costly, time-consuming, and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***Competing generic medicinal products or biosimilars may be approved.***

In the E.U., there exists a process for approval of generic biological medicinal products once patent protection and other forms of data and market exclusivity have expired. Arrangements for approval of generic biologics products exist in the United States, as well. Other jurisdictions are considering adopting legislation that would allow the approval of generic biological medicinal products. If generic medicinal products are approved, competition from such products may substantially reduce sales of our products.

***Public opinion and scrutiny of cell-based immunotherapy approaches may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.***

Our platform utilizes a relatively novel technology involving the genetic modification of human cells and utilization of those modified cells in other individuals, and no NK cell-based immunotherapy has been approved to date. Public perception may be influenced by claims, such as claims that cell-based immunotherapy is unsafe or unethical, and our approach may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion could have an adverse effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our potential product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates.

**Risks Relating to Government Regulation**

***We may fail to obtain or may experience delays in obtaining regulatory approval to market aNK cells or platform products, which will significantly harm our business.***

We do not have the necessary approval to market or sell aNK cells or platform products in the United States or any foreign market. Before marketing aNK cell product candidates, we must successfully complete extensive preclinical studies and clinical trials and rigorous regulatory approval procedures. We cannot assure you that we will apply for or obtain the necessary regulatory approval to commercialize aNK cell product candidates in a timely manner, or at all.

Conducting clinical trials is uncertain and expensive and often takes many years to complete. The results from preclinical testing and early clinical trials are often not predictive of results obtained in later clinical trials. In conducting clinical trials, we may fail to establish the effectiveness of aNK cells for the targeted indication or we may discover unforeseen side effects. Moreover, clinical trials may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Clinical trials are also often subject to unanticipated delays. In addition, aNK cells are produced in small scale cell culture systems and we may be unable to adapt the production method to large scale production systems. Also, patients participating in the trials may die before completion of the clinical trial or suffer adverse medical effects unrelated to treatment with aNK cells. This could delay or lead to termination of our clinical trials. A number of companies in the biotechnology industry have suffered significant setbacks in every stage of clinical trials, even in advanced clinical trials after positive results in earlier clinical trials.

To date, the FDA has approved only a few cell-based therapies for commercialization. The processes and requirements imposed by the FDA may cause delays and additional costs in obtaining regulatory approvals for our product candidates. Because our aNK cell therapy is novel, and cell-based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like aNK cells. This inexperience may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of aNK cells. In addition, the following factors may impede or delay our ability to obtain timely regulatory approvals, if at all:

- our limited experience in filing and pursuing Biologics License Applications, or BLAs, necessary to gain regulatory approvals related to genetically modified cancer cell line therapies;
- any failure to develop substantial evidence of clinical efficacy and safety, and to develop quality standards;
- a decision by us or regulators to suspend or terminate our clinical trials if the participating patients are being exposed to unacceptable health risks;
- regulatory inspections of our clinical trials, clinical trial sites or manufacturing facilities, which may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials if investigators find us not to be in compliance with applicable regulatory requirements;
- our ability to produce sufficient quantities of aNK cells to complete our clinical trials;
- varying interpretations of the data generated from our clinical trials; and
- changes in governmental regulations or administrative action.

Any delays in, or termination of, our clinical trials could materially and adversely affect our development and collaboration timelines, which may cause our stock price to decline. If we do not complete clinical trials for aNK cells and seek and obtain regulatory approvals, we may not be able to recover any of the substantial costs we have invested in the development of aNK cells.

***Even if we obtain regulatory approvals for aNK cells, those approvals and ongoing regulation of our products may limit how we manufacture and market our products, which could prevent us from realizing the full benefit of our efforts.***

If we obtain regulatory approvals, aNK cells, our aNK products, and our manufacturing facilities will be subject to continual regulatory review, including periodic unannounced inspections, by the FDA and other United States and foreign regulatory authorities. In addition, regulatory authorities may impose significant restrictions on the indicated uses or impose ongoing requirements for potentially costly post-approval studies. aNK cells and other product candidates would also be subject to ongoing FDA requirements governing the labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information. These and other factors may significantly restrict our ability to successfully commercialize aNK cells and our aNK cell therapies.

Manufacturers of biopharmaceutical products and their facilities, vendors and suppliers are subject to continual review and periodic unannounced inspections by the FDA and other regulatory authorities for compliance with current Good Manufacturing Practices, or cGMP, regulations, which include requirements relating to quality control and quality assurance as well as to the corresponding maintenance of records and documentation. Furthermore, our manufacturing facilities must be approved by regulatory agencies before these facilities can be used to manufacture aNK cells and related therapies, and they will also be subject to additional regulatory inspections. Any material changes we may make to our manufacturing process or to the components used in our products may require additional prior approval by the FDA and state or foreign regulatory authorities. Failure to comply with FDA or other applicable regulatory requirements may result in criminal prosecution, civil penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market.

We must also report adverse events that occur when our products are used. The discovery of previously unknown problems with aNK cells and therapies or our manufacturing facilities may result in restrictions or sanctions on our products or manufacturing facilities, including withdrawal of our products from the market or suspension of manufacturing. Regulatory agencies may also require us to reformulate our products, conduct additional clinical trials, make changes in the labeling of our product or obtain re-approvals. This may cause our reputation in the market place to suffer or subject us to lawsuits, including class action suits.

In addition, if we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters that can produce adverse publicity;
- impose civil or criminal penalties;
- suspend regulatory approval;

- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- seize or detain products or request us to initiate a product recall; or
- pursue and obtain an injunction.

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

Obtaining and maintaining regulatory approval of 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 of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the product, manufacturing, and in many cases reimbursement 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 some cases, the price that we intend to charge for our products is also subject to approval by regulatory authorities.

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 and/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.

***We may seek orphan drug status or breakthrough therapy designation for one or more of our product candidates, but even if either is granted, we may be unable to maintain any benefits associated with breakthrough therapy designation or orphan drug status, including market exclusivity.***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for a disease or condition will be recovered from sales in the United States for that drug or biologic. If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full Biologics License Application, or BLA, to market the same drug or biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. In 2012, the FDA established a Breakthrough Therapy Designation which is intended to expedite the development and review of products that treat serious or life-threatening conditions.

We may seek orphan drug status for one or more of our products candidates, but exclusive marketing rights in the United States may be lost if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, we may seek breakthrough therapy designation for one or more of our product candidates, but there can be no assurance that we will receive such designation.

***We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.***

A biopharmaceutical product cannot be marketed in the United States or other countries until we have completed rigorous and extensive regulatory review processes, including review and approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or the USPTO. The FDA may object to a product brand name if they believe the name creates potential for confusion or inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

***Coverage and reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance.***

There is significant uncertainty related to the third-party coverage and reimbursement of newly approved drugs. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, market acceptance and sales of our products, if approved, in both domestic and international markets will depend significantly on the availability of adequate coverage and reimbursement from third-party and/or government payors for any of our products and may be affected by existing and future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will cover and establish approved lists, known as formularies, and establish payment levels for such drugs. Formularies may not include all FDA-approved drugs for a particular indication. Private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment under Medicare Part D may result in a similar reduction in payments from non-governmental payors. We cannot be certain that coverage and adequate reimbursement will be available for any of our products, if approved, or that such coverage and reimbursement will be authorized in a timely fashion. Also, we cannot be certain that reimbursement policies will not reduce the demand for, or the price paid for, any of our products, if approved. If reimbursement is not available or is available on a limited basis for any of our products, if approved, we may not be able to successfully commercialize any such products.

Reimbursement by a third-party or government payor may depend upon a number of factors, including, without limitation, the third-party or government payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or to have pricing set at a satisfactory level. If reimbursement of our products, if any, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels such as may result where alternative or generic treatments are available, we may be unable to achieve or sustain profitability.

Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.



In the United States, third-party payors include federal and state healthcare programs, government authorities, private managed care providers, private health insurers, and other organizations. No uniform policy of coverage and reimbursement for products exists among third-party payors, and third-party payors are increasingly challenging the price, examining the medical necessity, and reviewing the cost-effectiveness of medical drug products and medical services, in addition to questioning their safety and efficacy. 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 obtained. We or our collaborators may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals.

In some foreign countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our products to other available therapies. If reimbursement of any of our products, if approved, is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability of our products in such country.

***Recent legislative and regulatory activity may exert downward pressure on potential pricing and reimbursement for our products, if approved, that could materially affect the opportunity to commercialize.***

The United States and several other jurisdictions are considering, or have already enacted, a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell any of our products profitably, if approved. Among policy-makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our products, if approved;
- our ability to set a price that we believe is fair for any of our products, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In March 2010, ACA became law in the United States. The goal of ACA is to reduce the cost of healthcare, broaden access to health insurance, constrain healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry, impose additional health policy reforms, and substantially change the way healthcare is financed by both governmental and private insurers. While we cannot predict what impact on federal reimbursement policies this legislation will have in general or on our business specifically, ACA may result in downward pressure on pharmaceutical reimbursement, which could negatively affect market acceptance of any of our products, if they are approved. Provisions of ACA relevant to the pharmaceutical industry include the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, not including orphan drug sales;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions to report annually certain financial arrangements with physicians and teaching hospitals, as defined in ACA and its implementing regulations, including reporting any payment or "transfer of value" provided to physicians and teaching hospitals and any ownership and investment interests held by physicians and their immediate family members during the preceding calendar year;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives 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.

***We are subject to governmental export and import controls that could impair our ability to compete in international markets due to licensing requirements and subject us to liability if we are not in compliance with applicable laws.***

Our products and solutions are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls. Exports of our products and solutions outside of the United States must be made in compliance with these laws and regulations. If we fail to comply with these laws and regulations, we and certain of our employees could be subject to substantial civil or criminal penalties, including the possible loss of export or import privileges; fines, which may be imposed on us and responsible employees or managers; and, in extreme cases, the incarceration of responsible employees or managers.

In addition, changes in our products or solutions or changes in applicable export or import laws and regulations may create delays in the introduction, provision, or sale of our products and solutions in international markets, prevent customers from using our products and solutions or, in some cases, prevent the export or import of our products and solutions to certain countries, governments or persons altogether. Any limitation on our ability to export, provide, or sell our products and solutions could adversely affect our business, financial condition and results of operations.

***We are subject to U.S. and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.***

We are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and possibly other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We currently use contract research organizations abroad for clinical trials. In addition, we may engage third party intermediaries to sell our products and solutions abroad once we enter a commercialization phase for our product candidates and/or to obtain necessary permits, licenses, and other regulatory approvals. We or our third-party intermediaries may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners, and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

We adopted an anti-corruption policy in connection with the consummation of the initial public offering of our common stock in July 2015. The anti-corruption policy mandates compliance with the FCPA and other anti-corruption laws applicable to our business throughout the world. However, there can be no assurance that our employees and third party intermediaries will comply with this policy or such anti-corruption laws. Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other investigations, or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

### **Risks Relating to Our Intellectual Property**

***If our efforts to protect the intellectual property related to our product candidates are not adequate, we may not be able to compete effectively in our market.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technology. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in the market. We believe that we have worldwide commercial rights to the NK-92 cell line and we believe that we control commercial use of our aNK cells in key territories. We have developed and in-licensed numerous patents and patent applications and we possess substantial know-how and trade secrets relating to the development and commercialization of Natural Killer cell-based immunotherapy product candidates, including related manufacturing processes and technology. Our owned and licensed patent portfolio consists of patents and pending patent applications in the U.S. disclosing subject matter directed to certain of our proprietary technology, inventions, and improvements and our most advanced product candidates, as well as licensed and owned patents and pending applications in jurisdictions outside of the U.S., that, in many cases, are counterparts to the foregoing U.S. patents and patent applications. We believe we have intellectual property rights that are necessary to commercialize aNK cells. However, our patent applications may not result in issued patents, and, even if issued, the patents may be challenged and invalidated. Moreover, our patents and patent applications may not be sufficiently broad to prevent others from practicing our technologies or developing competing products. We also face the risk that others may independently develop similar or alternative technologies or may design around our proprietary property.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. 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, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, etc., although we are unaware of any such defects that we believe are of material import. If we or our current licensors, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. 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. 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. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

The strength of patents in the biopharmaceutical field involves complex legal and scientific questions and can be uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law or rules in ways affecting the scope or validity of issued patents. The patent applications that we own or in-license may fail to result in issued patents in the United States or foreign countries with claims that cover our product candidates. Even if patents do successfully issue from the patent applications that we own or in-license, third parties may challenge the validity, enforceability or scope of such patents, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be challenged, also known as opposed, by any person within nine months from the publication of their grant. Any successful challenge to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidates. Furthermore, even if they are unchallenged, our patents may not adequately protect our product candidates, provide exclusivity for our product candidates, or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents we hold or pursue with respect to our product candidates is challenged, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize our product candidates.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its earliest effective non-provisional filing date. 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, if we encounter delays in our development efforts, including our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced.

In addition to the protection afforded by patents, we also rely on trade secret protection to protect proprietary know-how that may not be patentable or that we elect not to patent, processes for which patents may be difficult to obtain or enforce, and any other elements of our product candidates, and our product development processes (such as a manufacturing and formulation technologies) that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. If the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating any trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could significantly affect our competitive position and may have a material adverse effect on our business. Furthermore, trade secret protection does not prevent competitors from independently developing substantially equivalent information and techniques and we cannot guarantee that our competitors will not independently develop substantially equivalent information and techniques. The FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

In an effort to protect our trade secrets and other confidential information, we require our employees, consultants, advisors, and any other third parties that have access to our proprietary know-how, information or technology, for example, third parties involved in the formulation and manufacture of our product candidates, and third parties involved in our clinical trials to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual's relationship with us be kept confidential and not disclosed to third parties. However, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed despite having such confidentiality agreements. Adequate remedies may not exist in the event of unauthorized use or disclosure of our trade secrets. In addition, in some situations, these confidentiality agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, or advisors have previous employment or consulting relationships. To the extent that our employees, consultants or contractors use any intellectual property owned by third parties in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. If we are unable to prevent unauthorized material disclosure of our trade secrets to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity, and therefore, is costly, time-consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, recent U.S. Supreme Court rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or the American Invents Act, or AIA, was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO has developed regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA. It still remains unclear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “first-inventor-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. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications.

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.

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

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications directed to our product candidates, our competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on our business.

***Third-party claims alleging intellectual property infringement may adversely affect our business.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties, for example, the intellectual property rights of competitors. Our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidates may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party, for example a competitor in our market, might assert are infringed by our product candidates. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our product candidates. Nevertheless, we are not aware of any issued patents that we believe would prevent us from marketing our product candidates, if approved. There may also be patent applications that have been filed but not published that, when issued as patents, could be asserted against us.

Third parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Defense of these claims, regardless of their merit, would cause us to incur substantial expenses and, and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us by a third party, we may have to (1) pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed the third party's patents; (2) obtain one or more licenses from the third party; (3) pay royalties to the third party; and/or (4) redesign any infringing products. Redesigning any infringing products may be impossible or require substantial time and monetary expenditure. Further, we cannot predict whether any required license would be available at all or whether it would be available on commercially reasonable terms. In the event that we could not obtain a license, we may be unable to further develop and commercialize our product candidates, which could harm our business significantly. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms.

Defending ourselves or our licensors in litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property or the patents of our licensors, which could be expensive and time consuming.***

Third parties may infringe or misappropriate our intellectual property, including our existing patents, patents that may issue to us in the future, or the patents of our licensors to which we have a license. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. Further, we may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Generic drug manufacturers may develop, seek approval for, and launch generic versions of our products. If we file an infringement action against such a generic drug manufacturer, that company may challenge the scope, validity or enforceability of our or our licensors' patents, requiring us and/or our licensors to engage in complex, lengthy and costly litigation or other proceedings.

For example, if we or one of our licensors initiated legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidates is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent.

In addition, within and outside of the United States, there has been a substantial amount of litigation and administrative proceedings, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in various foreign jurisdictions, regarding patent and other intellectual property rights in the biopharmaceutical industry. Recently, the AIA introduced new procedures including inter partes review and post grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future, including those that patents perceived by our competitors as blocking entry into the market for their products, and the outcome of such challenges.

In March 2009, we received a final rejection in one of our original patent applications pertaining to certain limited methods of use claims for NK-92 from the USPTO (but the USPTO allowed claims on all of the other proposed claims, including other methods of use). We filed a Notice of Appeal to the USPTO Board of Appeals and Interferences and a Decision on Appeal was rendered in the fall of 2013. That decision reversed the Examiner's rejection of the claim to certain limited methods of use with NK-92, but affirmed the Examiner's rejection of the remaining patent claims. In December 2013, we brought an action in the U.S. District Court for the Eastern District of Virginia to review the decision of the USPTO as we disagreed with the decision as to the certain limited non-allowed claims. On September 2, 2015, the U.S. District Court granted the USPTO's motion for summary judgment. We are in the process of appealing the decision.

Such litigation and administrative proceedings could result in revocation of our patents or amendment of our patents such that they do not cover our product candidates. They may also put our pending patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates. The outcome following legal assertions of invalidity and unenforceability 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. Additionally, it is also possible that prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, may, nonetheless, ultimately be found by a court of law or an administrative panel to affect the validity or enforceability of a claim, for example if a priority claim is found to be improper. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Enforcing our or our licensor's intellectual property rights through litigation is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, during the course of litigation or administrative proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

***If we fail to comply with our obligation in any of the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.***

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. We rely on our exclusive license from Hans Klingemann, M.D., Ph.D., one of our founders and the inventor of our aNK cell therapy, and may rely on our exclusive licenses from Rush University Medical Center and other licensors such as Fox Chase Cancer Research Center and the University Health Network. If we fail to comply with the diligence obligations or otherwise materially breach our license agreement, and fail to remedy such failure or cure such breach, the licensor may have the right to terminate the license.

Our license agreement with Dr. Klingemann, as amended, is effective for 15 years following the first commercial sale of a product based on the license and may be terminated earlier by either party for material breach. Under the license agreement we have the right to enforce the licensed patents. At the end of the relevant 15 year period, we will have a perpetual, irrevocable, fully-paid royalty-free, exclusive license. Our license agreement with Rush University Medical Center terminates on the 12th anniversary of our first payment of royalties, at which point the license is deemed perpetual, irrevocable, fully-paid royalty-free, exclusive license, and may be terminated earlier by either party for material breach.

Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our right to sublicense intellectual property rights to third parties under collaborative development relationships; and
- 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.

While we would expect to exercise all rights and remedies available to us, including seeking to cure any breach by us, and otherwise seek to preserve our rights under the patents licensed to us, we may not be able to do so in a timely manner, at an acceptable cost or at all. Generally, the loss of any one of our current licenses, or any other license we may acquire in the future, could materially harm our business, prospects, financial condition and results of operations.

***Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property, which could limit our ability to compete.***

Because we operate in the highly technical field of research and development, we rely in part on trade secret protection in order to protect our proprietary trade secrets and unpatented know-how. However, trade secrets are difficult to protect, and we cannot be certain that others will not develop the same or similar technologies on their own. We have taken steps, including entering into confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors, to protect our trade secrets and unpatented know-how. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. We also typically obtain agreements from these parties which provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, these agreements may not be honored and may not effectively assign intellectual property rights to us. Enforcing a claim that a party illegally obtained and is using our trade secrets or know-how is difficult, expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets or know-how. The failure to obtain or maintain trade secret protection could adversely affect our competitive position.

***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 biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our business. 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.

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

We strive to control cell line distribution as well as limit commercial use through licenses and material transfer agreements with third parties in addition to its patents and patent applications. However, a company may illicitly obtain our cells or create their own modified variants and attempt to commercialize them in foreign countries where we do not have any patents or patent applications where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries. For example, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of a claimed drug. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as 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. 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 on infringing activities is inadequate. 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 and other intellectual property protection, particularly those relating to pharmaceuticals, 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. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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 own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

## **Risks Relating to Our Common Stock**

***Our Chairman and Chief Executive Officer and entities affiliated with him collectively own a significant majority of our common stock and will exercise significant influence over matters requiring stockholder approval, regardless of the wishes of other stockholders.***

As of March 31, 2016, our Chairman and Chief Executive Officer, Patrick Soon-Shiong, M.D., and entities affiliated with him, collectively own approximately 58.9% of the outstanding shares of our common stock. Additionally, Dr. Soon-Shiong is the owner of options, a warrant and restricted stock units to purchase an aggregate of 20.7 million shares of our common stock which would give him and his affiliates ownership of approximately 62.4% of our outstanding shares of common stock if they were fully vested and exercised in full. In addition, pursuant to the Nominating Agreement between us and Cambridge Equities, LP, or Cambridge, an entity that Dr. Soon-Shiong controls, Cambridge has the ability to designate one director to be nominated for election to our board of directors for as long as Cambridge continues to hold at least 20% of the issued and outstanding shares of our common stock. Dr. Soon-Shiong was selected by Cambridge to hold this board seat. Dr. Soon-Shiong and his affiliates will therefore have significant influence over management and significant control over matters requiring stockholder approval, including the annual election of directors and significant corporate transactions, such as a merger or other sale of our company or its assets, for the foreseeable future. This concentrated control will limit stockholders' ability to influence corporate matters and, as a result, we may take actions that our stockholders do not view as beneficial. As a result, the market price of our common stock could be adversely affected.

***We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.***

Prior to our initial public offering in July 2015, there was no public market for our common stock. Although our common stock is listed on The NASDAQ Global Select Market, the market for our shares has demonstrated varying levels of trading activity. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

***The market price of our common stock has been and may continue to be volatile.***

The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. A certain degree of market price volatility may be attributable to being a newly public company. The market price of our common stock has been and may continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including:

- the commencement, enrollment or results of the planned clinical trials of our product candidates or any 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, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- adverse results or delays in clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates

- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- 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 by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- our ability to effectively manage our growth;
- variations in our quarterly operating results;
- our cash position;
- announcements that our revenue or income are below or that costs or losses are greater than analysts' expectations;
- 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;
- general economic slowdowns;
- sales of large blocks of our common stock;
- fluctuations in stock market prices and volumes;
- 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; and
- the other factors described in this "Risk Factors" section.

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.

***Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plan and the warrant held by our Chairman and Chief Executive Officer, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market the market price of our common stock could decline significantly. In particular, the options, warrant, and restricted stock units to purchase or receive common stock held by our Chairman and Chief Executive Officer at March 31, 2016 may entitle him to acquire up to an aggregate of 20.7 million shares of our common stock, or approximately 25.2% of our outstanding common stock. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of approximately 52.7 million shares of our common stock, including shares issuable upon the exercise of outstanding options and warrants, are entitled to certain rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by our affiliates as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the market price of our common stock.

In addition, we expect that additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock, including shares of common stock sold in this offering.

***We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to new compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.***

As a public company listed in the United States, and increasingly after we are no longer an “emerging growth company,” we have incurred and will continue to incur significant additional legal, accounting and other expenses that we did not incur as a private company. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including Sarbanes-Oxley and regulations implemented by the Securities and Exchange Commission or SEC, and The NASDAQ Stock Market, or NASDAQ, may increase legal and financial compliance costs and make some activities more time consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We intend to invest resources to create a larger finance function with additional personnel to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management’s time and attention from revenue-generating activities to compliance activities. If notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

As a public company in the United States, we are required, pursuant to Section 404 of Sarbanes-Oxley, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. We must disclose any material weaknesses identified by our management in our internal control over financial reporting, and, when we are no longer an “emerging growth company,” we will need to provide a statement that our independent registered public accounting firm has issued an opinion on our internal control over financial reporting. As discussed below, we have identified certain material weaknesses in our internal controls in connection with the preparation of our condensed consolidated financial statements for the quarters ended June 30, 2015 and September 30, 2015 and for the year ended December 31, 2015. Such remediation efforts are ongoing. We expect that our first report on compliance with Section 404 will be furnished in connection with our financial statements for the year ending December 31, 2016.

The controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms. We are in the early stages of conforming our internal control procedures to the requirements of Section 404 and we may not be able to complete our evaluation, testing and any required remediation needed to comply with Section 404 in a timely fashion. Our independent registered public accounting firm was not engaged to perform an audit of our internal control over financial reporting for the year ended December 31, 2015 or for any other period. Accordingly, no such opinion was expressed.

Even after we develop these new procedures, these new controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate and material weaknesses in our internal control over financial reporting may be discovered. We may err in the design or operation of our controls, and all internal control systems, no matter how well designed and operated, can provide only reasonable assurance that the objectives of the control system are met. Because there are inherent limitations in all control systems, there can be no absolute assurance that all control issues have been or will be detected. If we are unable, or are perceived as unable, to produce reliable financial reports due to internal control deficiencies, investors could lose confidence in our reported financial information and operating results, which could result in a negative market reaction.

To fully comply with Section 404, we will need to retain additional employees to supplement our current finance staff, and we may not be able to do so in a timely manner, or at all. In addition, in the process of evaluating our internal control over financial reporting, we expect that certain of our internal control practices will need to be updated to comply with the requirements of Section 404 and the regulations promulgated thereunder, and we may not be able to do so on a timely basis, or at all. In the event that we are not able to demonstrate compliance with Section 404 in a timely manner, or are unable to produce timely or accurate financial statements, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or NASDAQ, and investors may lose confidence in our operating results and the price of our common stock could decline. Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and we could lose investor confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our common stock and our ability to access the capital markets.

We also expect that being a public company will make it more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

***We have identified certain material weaknesses in our internal control over financial reporting. Failure to maintain effective internal controls could cause our investors to lose confidence in us and adversely affect the market price of our common stock. If our internal controls are not effective, we may not be able to accurately report our financial results or prevent fraud.***

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the preparation of our financial statements for our initial public offering, we concluded that there were material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. We have identified certain material weaknesses in our internal controls resulting from:

- our chief financial officer having almost complete responsibility for the processing of financial information; and
- our finance department not having adequate staff to process in a timely manner complex, non-routine transactions.

While we have designed and implemented, or expect to implement, measures that we believe address or will address these control weaknesses, we continue to develop our internal controls, processes and reporting systems by, among other things, hiring qualified personnel with expertise to perform specific functions, implementing software systems to manage our revenue and expenses and to allow us to budget, undertaking multi-year financial planning and analyses and designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight. We commenced measures to remediate the identified material weaknesses during the second quarter of 2015 by hiring financial consultants and continue to add experienced resources through the fourth quarter of 2015. These remediation efforts were not fully complete as of December 31, 2015, and have continued through the first quarter of 2016. We expect to incur additional costs to remediate these weaknesses, primarily personnel costs and external consulting fees. We may not be successful in implementing these systems or in developing other internal controls, which may undermine our ability to provide accurate, timely and reliable reports on our financial and operating results. Further, we will not be able to fully assess whether the steps we are taking will remediate the material weaknesses in our internal control over financial reporting until we have completed our implementation efforts and sufficient time passes in order to evaluate their effectiveness. In addition, if we identify additional material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. Moreover, in the future we may engage in business transactions, such as acquisitions, reorganizations or implementation of new information systems that could negatively affect our internal control over financial reporting and result in material weaknesses.

Our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional control deficiencies amounting to material weaknesses may have been identified. If we identify new material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, we may be late with the filing of our periodic reports, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected. As a result of such failures, we could also become subject to investigations by NASDAQ, the SEC, or other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation, financial condition or divert financial and management resources from our core business.

***We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.***

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends in the foreseeable future. The payment of dividends on our common stock will depend on earnings, financial condition and other business and economic factors affecting us at such time as the board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on your investment will only occur if our stock price appreciates.

***Because we are relying on the exemptions from corporate governance requirements as a result of being a “controlled company” within the meaning of the NASDAQ listing standards, you do not have the same protections afforded to stockholders of companies that are subject to such requirements.***

Our Chairman and Chief Executive Officer, Dr. Patrick Soon-Shiong, and entities affiliated with him, control a majority of our common stock. As a result, we are a “controlled company” within the meaning of the NASDAQ listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a “controlled company” and may elect not to comply with certain NASDAQ corporate governance requirements, including (1) the requirement that a majority of the board of directors consist of independent directors and (2) the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee’s purpose and responsibilities. We have elected not to have a nominating and corporate governance committee in reliance on the “controlled company” exemptions. Accordingly, you do not have the same protections afforded to stockholders of companies that are subject to all of the NASDAQ corporate governance requirements.

***We are an “emerging growth company,” and the reduced disclosure requirements applicable to emerging growth companies could make our common stock could be less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act enacted in April 2012, or the JOBS Act, and may remain an “emerging growth company” for up to five years following the completion of our initial public offering, or December 31, 2020, although, if we have more than \$1.0 billion in annual revenue, the market value of our common stock that is held by non-affiliates exceeds \$700.0 million as of June 30 of any year, or we issue more than \$1.0 billion of non-convertible debt over a three-year period before the end of that five-year period, we would cease to be an “emerging growth company” as of the following December 31. For as long as we remain an “emerging growth company,” we are permitted and intend to continue to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not “emerging growth companies.” These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s discussion and analysis of financial condition and results of operations” disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We have taken advantage of reduced reporting requirements in our public filings. In particular, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards, delaying the adoption of these accounting standards until they would apply to private companies. We have irrevocably elected not to avail ourselves of this exemption and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies. Investors may find our common stock less attractive as a result of our reliance on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and the market price of our common stock may be reduced or more volatile.

***Our ability to use our net operating loss carryforwards, or NOLs, and certain other tax attributes to offset future taxable income may be subject to certain limitations.***

As of December 31, 2015 we had U.S. federal, state and foreign NOLs of approximately \$31.6 million, \$28.1 million and \$0.2 million, respectively, which expire in various years beginning in 2015, if not utilized. As of December 31, 2015, we had minimal research and development tax credit carryforwards. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. Although we have not yet conducted a study, we believe that we have recently undergone one or more ownership changes, and accordingly our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability will be limited. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

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

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

***We are not subject to the provisions of Section 203 of the Delaware General Corporation Law, which could negatively affect your investment.***

We elected in our amended and restated certificate of incorporation to not be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns (or, in certain cases, within three years prior, did own) 15% or more of the corporation’s voting stock. Our decision not to be subject to Section 203 will allow, for example, our Chairman and Chief Executive Officer (who with members of his immediate family and entities affiliated with him owned approximately 58.9% of our common stock as of March 31, 2016) to transfer shares in excess of 15% of our voting stock to a third-party free of the restrictions imposed by Section 203. This may make us more vulnerable to takeovers that are completed without the approval of our board of directors and/or without giving us the ability to prohibit or delay such takeovers as effectively.

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

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

- a requirement that special meetings of stockholders be called only by the board of directors, the president or the chief executive officer;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

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

To the extent that a claim for indemnification is brought by any of our directors or officers, it would reduce the amount of funds available for use in our business.

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

***(a) Recent Sale of Unregistered Securities***

*None*

***(b) Use of Proceeds from Public Offering of Common Stock***

On July 27, 2015, our Registration Statement on Form S-1, as amended (Reg. No. 333- 205124) was declared effective in connection with the initial public offering of our common stock, pursuant to which we sold 9,531,200 shares at a price to the public of \$25.00 per share. The offering closed on July 31, 2015, as a result of which we received net proceeds of approximately \$221.5 million after underwriting discounts and offering expenses. Merrill Lynch, Pierce, Fenner & Smith, Incorporated, Citigroup Global Markets Inc., Jefferies LLC and Piper Jaffray & Co. acted as joint book-running managers for the offering, and MLV & Co. LLC Inc. acted as co-manager. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates. In November 2015, the board of directors approved a share repurchase program allowing the Chief Executive Officer or Chief Financial Officer, on behalf of the Company, to repurchase from time to time, in the open market or in privately negotiated transactions, up to \$50 million of our outstanding shares of common stock, exclusive of any commissions, markups or expenses. We may use the proceeds from the initial public offering to conduct such repurchases. Accordingly, our use of proceeds from the initial public offering is as follows:

- approximately \$6.0 million to fund expenses in connection with our Phase II clinical trial for our aNK product candidate for Merkel cell carcinoma, which we expect will be sufficient to fund the clinical trial;
- approximately \$10.0 million to fund expenses in connection with our planned Phase I/II clinical trial for Rituxan-haNK for solid tumors, which we expect will be sufficient to fund the clinical trial;
- approximately \$14.0 million to fund expenses in connection with our planned Phase I/II clinical trials for CD33.taNK for acute myeloid leukemia and HER2.taNK for HER2 positive breast cancers, which we expect will be sufficient to fund the clinical trials;

- approximately \$10.0 million to establish our planned manufacturing facility and processes and the hiring of additional personnel; and
- the remaining amounts for other research and development activities, working capital and general corporate purposes, including up to \$50 million to repurchase our common stock (exclusive of any commissions, markups or expenses) from time to time, in the open market or in privately negotiated transactions.

We may also use a portion of the net proceeds from the offering and our existing cash to in-license, acquire or invest in complementary business, technologies, products or assets. However, we have no current plans, commitments or obligations to do so.

**(c) Issuer Purchases of Equity Securities**

*Stock Repurchase*—In November 2015, the board of directors approved a share repurchase program (the 2015 Share Repurchase Program) allowing the CEO or CFO, on behalf of the Company, to repurchase from time to time, in the open market or in privately negotiated transactions, up to \$50 million of the Company’s outstanding shares of common stock, exclusive of any commissions, markups or expenses. The timing and amounts of any purchases will be based on market conditions and other factors, including price, regulatory requirements and other corporate considerations. The program does not require the purchase of any minimum number of shares and may be suspended, modified or discontinued at any time without prior notice. The Company expects to finance the purchases with existing cash balances.

During the three months ending March 31, 2016, 300,000 shares were repurchased and retired at a total price of \$2.6 million. There were no commissions as it was a private repurchase at the then current market price. At March 31, 2016, \$47.4 million remained authorized for repurchase under the Company’s stock repurchase program.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES.**

None.

**ITEM 4. MINE SAFETY DISCLOSURES.**

Not applicable.

**ITEM 5. OTHER INFORMATION.**

**Appointment of Sonja Nelson as VP, Corporate Controller & Chief Accounting Officer**

On May 13, 2016, we appointed Sonja Nelson as VP, Corporate Controller and Chief Accounting Officer.

Ms. Nelson, age 43, has served as our VP/ Corporate Controller since November 2015. Prior to joining the Company, Ms. Nelson was Vice President and Corporate Controller at AltheaDx, Inc., a molecular diagnostics company and was hired to prepare the company for an IPO, from July 2014 through October 2015. Previously, Ms. Nelson was Senior Director and Controller at Cadence Pharmaceuticals, Inc. from May 2012 through June 2014. Prior to that, Ms. Nelson was Director, General Accounting at Cricket Communications, Inc., a \$3 billion wireless services provider, from September 2008 through May 2012. Ms. Nelson started out her career with KPMG LLP, holds a Bachelor’s degree in accounting and taxation from the University of Applied Sciences in Pforzheim, Germany, and is a Certified Public Accountant.

Ms. Nelson does not have a family relationship with any member of the Board or any executive officer of the Company, and Ms. Nelson has not been a participant or had an interest in any transaction with the Company that is reportable under Item 404(a) of Regulation S-K.

**Compensation Arrangements with Sonja Nelson**

In connection with the appointment of Ms. Nelson to her position as the VP, Corporate Controller and Chief Accounting Officer, Ms. Nelson will receive an annual base salary of \$245,000 and will be eligible to receive an annual bonus with a target level of forty percent (40%) of her base salary. Ms. Nelson will also enter into the Company’s standard indemnification agreement in the form previously approved by the Board.

The foregoing description of Ms. Nelson’s compensation arrangement with the Company does not purport to be complete and is qualified in its entirety by reference to the full text of her offer letter from the Company, a copy of which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.



**Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

On May 12, 2016, the compensation committee of our board of directors approved bonus awards for Patrick Soon-Shiong, our Chairman and Chief Executive Officer, of \$300,000, for Barry J. Simon, our Chief Operating Officer, of \$177,750, and for Ms. Nelson of \$25,000.

**ITEM 6. EXHIBITS.**

The documents listed in the Exhibit Index, which follows the signature page of this Quarterly Report on Form 10-Q, are incorporated by reference or are filed with this Quarterly Report on Form 10-Q, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

**SIGNATURES**

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

NANTKWEST, INC.

Dated: May 16, 2016

By: /s/ Patrick Soon-Shiong  
Patrick Soon-Shiong  
Chief Executive Officer and Chairman  
*(Principal Executive Officer)*

By: /s/ Richard J. Tajak  
Richard J. Tajak  
Interim Chief Financial Officer  
*(Principal Financial and Accounting Officer)*

**EXHIBIT INDEX**

Exhibit Number	Description	Incorporated by Reference Herein			
		Form	File No.	Exhibit	Filing Date
10.1*†	Offer Letter between the Company and Sonja Nelson, dated April 7, 2016				
31.1*	Rule 13a-14(a) / 15(d)-14(a) Certification of Principal Executive Officer				
31.2*	Rule 13a-14(a) / 15(d)-14(a) Certification of Principal Financial Officer				
32.1**	Section 1350 Certification of Chief Executive Officer				
32.2**	Section 1350 Certification of Chief Financial Officer				
101.INS	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				

\* Filed herewith.

\*\* The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of NantKwest, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in such filing.

† Indicates a management contract or compensatory plan.



April 7, 2016

**PERSONAL AND CONFIDENTIAL**

Sonja Nelson

Re: Promotion

Dear Sonja,

We are pleased to inform you that subject to the approval of the Company's board of directors, your title will be Vice President, Corporate Controller and Chief Accounting Officer. You will receive a salary increase to an annual rate of \$245,000 effective April 1, 2016. This salary will be paid in accordance with the Company's regularly established payroll practice. The salary hereof is a gross amount, and the Company will be required to withhold from such amount deductions with respect to Federal, state and local taxes, FICA, unemployment compensation taxes and similar taxes, assessments or withholding requirements. You will continue to report to Richard Tajak, Chief Financial Officer.

I look forward to your continued growth within our organization. If you should have any questions, please contact me at [nantoniou@nantworks.com](mailto:nantoniou@nantworks.com) or 310-853-7812

Sincerely,

/s/ Nancy Valdivia Antoniou

Nancy Valdivia Antoniou  
Human Resources

cc: Personnel File

NantKwest Inc. | 9920 Jefferson Blvd, Culver City, CA 90232

[www.nantkwest.com](http://www.nantkwest.com)

**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF  
THE SARBANESOXLEY ACT OF 2002**

I, Patrick Soon-Shiong, certify that:

1. I have reviewed this Quarterly Report on Form 10Q of NantKwest, 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 13a15(e) and 15d15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 16, 2016

By: /s/ Patrick Soon-Shiong  
Patrick Soon-Shiong  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF  
THE SARBANESOXLEY ACT OF 2002**

I, Richard Tajak, certify that:

1. I have reviewed this Quarterly Report on Form 10Q of NantKwest, 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 13a15(e) and 15d15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 16, 2016

By: /s/ Richard Tajak  
Richard Tajak  
Chief Financial Officer  
(Principal Financial Officer)

**CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. § 1350, AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANESOXLEY ACT OF 2002**

I, Patrick Soon-Shiong, the chief executive officer of NantKwest, Inc. (the "Company"), certify for the purposes of 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:

- i. the Quarterly Report of the Company on Form 10Q for the quarter ended March 31, 2016 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 16, 2016

By: /s/ Patrick Soon-Shiong  
Patrick Soon-Shiong  
Chief Executive Officer



**CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. § 1350, AS ADOPTED  
PURSUANT TO SECTION 906 OF THE SARBANESOXLEY ACT OF 2002**

I, Richard Tajak, the chief financial officer of NantKwest, Inc. (the "Company"), certify for the purposes of 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:

- i. the Quarterly Report of the Company on Form 10Q for the quarter ended March 31, 2016 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- ii. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 16, 2016

By: /s/ Richard Tajak  
Richard Tajak  
Chief Financial Officer