

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, 2020

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)

Registrant's telephone number, including area code: (858) 633-0300

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	NK	The Nasdaq Stock Market LLC (Nasdaq Global Select Market)

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 every Interactive Data File required to be submitted 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 such files). YES NO

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

The number of shares of the Registrant's common stock outstanding as of May 8, 2020 was 98,508,958.

TABLE OF CONTENTS

	<u>Page</u>
<u>Part I—FINANCIAL INFORMATION</u>	
Item 1. Financial Statements	1
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	24
Item 3. Quantitative and Qualitative Disclosures about Market Risk	39
Item 4. Controls and Procedures	39
<u>Part II—OTHER INFORMATION</u>	
Item 1. Legal Proceedings	41
Item 1A. Risk Factors	41
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	81
Item 3. Defaults Upon Senior Securities	81
Item 4. Mine Safety Disclosures	81
Item 5. Other Information	81
Item 6. Exhibits	81
Signatures	82

PART I—FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

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

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,952	\$ 15,508
Prepaid expenses and other current assets (including related parties)	3,910	4,105
Marketable debt securities, available-for-sale	23,263	36,144
Total current assets	44,125	55,757
Marketable debt securities, noncurrent	—	1,497
Property, plant and equipment, net	58,539	60,501
Operating lease right-of-use assets, net (including related parties)	11,055	11,729
Equity investment	9,253	9,253
Other assets (including related parties)	4,051	4,386
Total assets	<u>\$ 127,023</u>	<u>\$ 143,123</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,148	\$ 1,749
Accrued expenses	6,634	5,343
Due to related parties	853	486
Other current liabilities (including related parties)	3,613	3,981
Total current liabilities	14,248	11,559
Operating lease liability, less current portion (including related parties)	10,180	10,885
Total liabilities	<u>24,428</u>	<u>22,444</u>
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, \$0.0001 par value; 500,000,000 shares authorized; 98,498,432 and 98,460,404 issued and outstanding as of March 31, 2020 and December 31, 2019	10	10
Additional paid-in capital	783,287	782,965
Accumulated other comprehensive loss	(128)	(105)
Accumulated deficit	(680,574)	(662,191)
Total stockholders' equity	102,595	120,679
Total liabilities and stockholders' equity	<u>\$ 127,023</u>	<u>\$ 143,123</u>

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

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

	Three Months Ended March 31,	
	2020	2019
Revenue	\$ 21	\$ 5
Operating expenses:		
Research and development (including amounts with related parties)	13,234	12,598
Selling, general and administrative (including amounts with related parties)	5,373	5,742
Total operating expenses	18,607	18,340
Loss from operations	(18,586)	(18,335)
Other income (expense):		
Investment income, net	178	370
Interest expense	(7)	(3)
Other income, net (including amounts with related parties)	32	47
Total other income	203	414
Loss before income taxes	(18,383)	(17,921)
Income tax benefit	—	36
Net loss	\$ (18,383)	\$ (17,885)
Net loss per share:		
Basic and diluted	\$ (0.19)	\$ (0.22)
Weighted-average number of shares during the period:		
Basic and diluted	98,472,641	81,261,302

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,	
	2020	2019
Net loss	\$ (18,383)	\$ (17,885)
Other comprehensive (loss) income, net of income taxes:		
Net unrealized (losses) gains on available-for-sale securities	(24)	61
Reclassification of net realized losses on available-for-sale securities included in net loss	1	—
Total other comprehensive (loss) income	(23)	61
Comprehensive loss	\$ (18,406)	\$ (17,824)

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount				
Balance at December 31, 2019	98,460,404	\$ 10	\$ 782,965	\$ (105)	\$ (662,191)	\$ 120,679
Stock-based compensation expense	—	—	445	—	—	445
Vesting of restricted stock units (RSUs)	63,750	—	—	—	—	—
Employee payroll taxes withheld related to vesting of RSUs	(25,722)	—	(123)	—	—	(123)
Other comprehensive loss, net	—	—	—	(23)	—	(23)
Net loss	—	—	—	—	(18,383)	(18,383)
Balance at March 31, 2020	<u>98,498,432</u>	<u>\$ 10</u>	<u>\$ 783,287</u>	<u>\$ (128)</u>	<u>\$ (680,574)</u>	<u>\$ 102,595</u>
	Common Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Paid-in	Other	Deficit	
			Capital	Comprehensive		
				Loss		
Balance at December 31, 2018	79,087,734	\$ 8	\$ 741,246	\$ (267)	\$ (594,981)	\$ 146,006
Stock-based compensation expense	—	—	1,351	—	—	1,351
Exercise of warrants	17,589,250	2	35,149	—	—	35,151
Exercise of stock options	1,986,300	—	4,070	—	—	4,070
Vesting of RSUs	49,775	—	—	—	—	—
Employee payroll taxes withheld related to vesting of RSUs and exercise of stock options	(38,906)	—	(26)	—	—	(26)
Cumulative effect of the adoption of the new lease standard	—	—	—	—	(920)	(920)
Other comprehensive income, net	—	—	—	61	—	61
Net loss	—	—	—	—	(17,885)	(17,885)
Balance at March 31, 2019	<u>98,674,153</u>	<u>\$ 10</u>	<u>\$ 781,790</u>	<u>\$ (206)</u>	<u>\$ (613,786)</u>	<u>\$ 167,808</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)

	Three Months Ended March 31,	
	2020	2019
Operating activities:		
Net loss	\$ (18,383)	\$ (17,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,217	2,395
Non-cash lease expense related to operating lease right-of-use assets	674	624
Stock-based compensation expense	445	1,351
Amortization of net premiums and discounts on marketable debt securities	45	41
Non-cash interest items, net	17	(95)
Loss on sales of marketable debt securities	1	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	244	80
Operating lease right-of-use assets, net	—	(247)
Other assets	335	8
Accounts payable	1,270	670
Accrued expenses and other liabilities	997	797
Due to related parties	300	(162)
Operating lease liabilities	(758)	(655)
Net cash used in operating activities	<u>(12,596)</u>	<u>(13,078)</u>
Investing activities:		
Purchases of property, plant and equipment	(146)	(2,104)
Purchases of marketable debt securities, available-for-sale	(10,300)	(50,273)
Sales/maturities of marketable debt securities	24,609	32,918
Net cash provided by (used in) investing activities	<u>14,163</u>	<u>(19,459)</u>
Financing activities:		
Proceeds from exercises of stock options and warrants	—	39,221
Net share settlement for restricted stock unit vesting and option exercises	(123)	(26)
Net cash (used in) provided by financing activities	<u>(123)</u>	<u>39,195</u>
Net increase in cash, cash equivalents, and restricted cash	1,444	6,658
Cash, cash equivalents, and restricted cash, beginning of period	15,687	17,000
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 17,131</u>	<u>\$ 23,658</u>

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

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

	<u>Three Months Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
Reconciliation of cash, cash equivalents, and restricted cash at end of period:		
Cash and cash equivalents	\$ 16,952	\$ 22,279
Restricted cash	179	1,379
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 17,131</u>	<u>\$ 23,658</u>
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	\$ 7	\$ 3
Income taxes	\$ —	\$ —
Supplemental disclosure of non-cash investing and financing activities:		
Property and equipment purchases included in accounts payable, accrued expenses, and other liabilities	\$ 182	\$ 2,031
Conversion of Viracta convertible notes and accrued interest into investment in equity securities of Viracta (Note 4)	\$ —	\$ 751
Unrealized (losses) gains on marketable debt securities	\$ (23)	\$ 118
Cashless exercise of stock options	\$ —	\$ 29

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

1. Description of Business

Organization

NantKwest, Inc., or NantKwest, 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. In March 2014, the company redomesticated from the State of Illinois to the State of Delaware and the Illinois company ceased to exist. We are a pioneering clinical-stage immunotherapy biotechnology company headquartered in San Diego, California with certain operations in Culver City and El Segundo, California and Woburn, Massachusetts. In these notes, the terms “we,” “our,” “the company” and “us” refer to NantKwest.

We are focused on harnessing the power of the innate immune system by using its natural killer cells, or NK cells, to treat cancer and viral infectious diseases. A critical aspect of our strategy is to invest significantly in innovating new therapeutic candidates, based upon our proprietary activated NK, or aNK, cell platform, and conducting clinical testing and scale manufacturing of our most promising biologic product candidates.

We hold the exclusive right to commercialize aNK cells, a commercially viable NK cell line, and a wide range of genetically modified derivatives capable of killing cancer and virally infected cells. We own corresponding United States, or U.S., and foreign composition and methods-of-use patents and applications covering the cells, improvements, methods of expansion and manufacture and use of aNK cells and their improvements as therapeutics to treat a spectrum of clinical conditions.

We also license exclusive commercial rights to a high-affinity CD16 receptor expressing enhancement of our aNK cell platform, covered in a portfolio of U.S. and foreign composition and methods-of-use patents and applications covering both the clinical use as a therapeutic to treat cancers in combination with antibody products, as well as the non-clinical use in laboratory testing of monoclonal antibodies. We have non-exclusively licensed or sub-licensed our high-affinity CD16 bearing aNK cell platform and corresponding intellectual property to numerous pharmaceutical and biotechnology companies for such non-clinical uses.

Liquidity

As of March 31, 2020, the company had an accumulated deficit of approximately \$680.6 million. We also had negative cash flow from operations of approximately \$12.6 million during the three months ended March 31, 2020. The company will likely need additional capital to further fund development of, and seek regulatory approvals for, our product candidates, and to begin to commercialize any approved products.

We are currently focused primarily on the development of immunotherapeutic treatments for cancers and debilitating viral infections using targeted cancer and viral killing cell lines, and we believe 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 our product candidates, if approved, fail to achieve market acceptance, we may never become profitable. Even if the company achieves profitability in the future, it may not be able to sustain profitability in subsequent periods. We intend to cover our future operating expenses through cash and cash equivalents and marketable debt 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 us when needed and, if available, financing may not be obtained on terms favorable to the company or its stockholders.

While we expect our existing cash, and cash equivalents and marketable debt securities, together with the ability to borrow from affiliated entities, will enable us to fund operations and capital expenditure requirements for at least the next 12 months, we may not have sufficient funds to reach commercialization. Failure to obtain adequate financing when needed may require us to delay, reduce, limit, or terminate some or all of our development programs or future commercialization efforts or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves, which could adversely affect our ability to operate as a going concern. If we raise additional funds from the issuance of equity securities, substantial dilution to existing stockholders may result. If we raise 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 our ability to operate our business.

2. Summary of Significant Accounting Policies

There have been no material changes in our significant accounting policies other than the adoption of accounting pronouncements described below under *Application of New or Revised Accounting Standards – Adopted*, as compared to the significant accounting policies described in our Annual Report on Form 10-K for the year ended December 31, 2019.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The condensed consolidated financial statements reflect all adjustments which are, in the opinion of management, necessary to present fairly the results for the interim periods presented and have been prepared on the same basis as the audited consolidated financial statements for the fiscal year ended December 31, 2019.

The condensed consolidated financial statements have been prepared assuming the company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or amounts and classification of liabilities that may result from the outcome of the uncertainty discussed in the Liquidity section of Note 1. We believe our existing cash, cash equivalents, and investments in marketable debt securities, and our ability to borrow from affiliated entities, will be sufficient to fund operations through at least the next 12 months following the issuance date of the financial statements based upon our Chairman and CEO's intent and ability to support the company's operations with additional funds, including loans from affiliated entities, as required. We may also seek to sell additional equity, through one or more follow-on public offerings, or in separate financings, or obtain a credit facility. However, we may not be able to secure such financing in a timely manner or on favorable terms. Without additional funds, we may choose to delay or reduce our operating or investment expenditures. Further, because of the risk and uncertainties associated with the commercialization of the company's product candidates in development, we may need additional funds to meet our needs sooner than planned. To date, the company's primary sources of capital were its initial public offering and the concurrent private placement of common shares. In addition, during the year ended December 31, 2019, our Chairman and CEO exercised warrants and options resulting in aggregate cash proceeds of \$39.2 million.

The unaudited condensed consolidated financial statements do not include all information and notes necessary for a complete presentation of results of income, comprehensive income, financial position, and cash flows in conformity with U.S. GAAP. Accordingly, these financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2019 included in our Annual Report on Form 10-K. Interim operating results are not necessarily indicative of operating results for the full year. The year-end consolidated balance sheet data was derived from our audited financial statements, but does not include all disclosures required by U.S. GAAP.

Principles of Consolidation and Equity Investments

The condensed consolidated financial statements include the accounts of NantKwest and its wholly owned subsidiaries. All intercompany amounts have been eliminated.

We apply the variable interest model under Accounting Standards Codification, or ASC, Topic 810, *Consolidation*, to any entity in which we hold an equity investment or to which we have the power to direct the entity's most significant economic activities and the ability to participate in the entity's economics. If the entity is within the scope of the variable interest model and meets the definition of a variable interest entity, or VIE, we consider whether we must consolidate the VIE or provide additional disclosures regarding our involvement with the VIE. If we determine that we are the primary beneficiary of the VIE, we will consolidate the VIE. This analysis is performed at the initial investment in the entity or upon any reconsideration event.

For entities we hold as an equity investment that are not consolidated under the VIE Model, we consider whether our investment constitutes ownership of a majority of the voting interests in the entity and therefore should be considered for consolidation under the voting interest model.

Unconsolidated equity investments in the common stock or in-substance common stock of an entity under which we are able to exercise significant influence, but not control, are accounted for using the equity method. Our ability to exercise significant influence is generally indicated by ownership of 20 to 50 percent interest in the voting securities of the entity.

All other unconsolidated equity investments on which we are not able to exercise significant influence will be subsequently measured at fair value with unrealized holding gains and losses included in other income, net on the condensed consolidated statements of operations. In the instance the equity investment does not have a readily determinable fair value and does not qualify for the practical expedient to estimate fair value in accordance with ASC 820, *Fair Value Measurement*, or ASC 820, we will apply the measurement alternative under ASC 321, *Investments—Equity Securities*, or ASC 321, pursuant to which we will measure the investment at its cost less impairment, adjusted for observable price changes in an orderly market for an identical or similar investment of the same issuer.

We own non-marketable equity securities that are accounted for using the measurement alternative under ASC 321 because the preferred stock held by us is not considered in-substance common stock and such preferred stock does not have a readily determinable fair value. All investments are reviewed on a regular basis for possible impairment. If an investment's fair value is determined to be less than its net carrying value, the investment is written down to its fair value. Such an evaluation is judgmental and dependent on specific facts and circumstances. Factors considered in determining whether an impairment indicator is present include: the investees' earnings performance and clinical trial performance, change in the investees' industry and geographic area in which it operates, offers to purchase or sell the security for a price less than the cost of the investment, issues that raise concerns about the investee's ability to continue as a going concern, and any other information that we may be aware of related to the investment. Factors considered in determining whether an observable price change has occurred include: the price at which the investee issues equity instruments similar to those of our investment and the rights and preferences of those equity instruments compared to ours.

Use of Estimates

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP 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, we evaluate our estimates, including those related to valuation of equity-based awards, deferred income taxes and related valuation allowances, preclinical and clinical trial accruals, impairment assessments, useful lives of long-lived assets, loss contingencies, and fair value measurements. We base our estimates on historical experience and on various other market-specific and relevant assumptions that we believe to be reasonable under the circumstances. Estimates are assessed each period and updated to reflect current information, such as the economic considerations related to the impact that the recent coronavirus disease (COVID-19) could have on our significant accounting estimates. Actual results could differ from those estimates.

Risks and Uncertainties

In March 2020, the World Health Organization declared the novel strain of coronavirus disease (SARS-CoV-2) outbreak a pandemic. To date, our operations have not been significantly impacted by the COVID-19 outbreak. However, we cannot at this time predict the specific extent, duration, or full impact that the COVID-19 outbreak may have on our financial condition and results of operations, including ongoing and planned clinical trials. The impact of the COVID-19 coronavirus outbreak on the financial performance of the company will depend on future developments, including the duration and spread of the outbreak and related governmental advisories and restrictions. These developments and the impact of COVID-19 on the financial markets and the overall economy are highly uncertain. If the financial markets and/or the overall economy are impacted for an extended period, our results may be adversely affected.

Contingencies

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause a change in the potential amount of the liability recorded or of the range of potential losses disclosed. Additionally, we record our rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and when receipt is deemed probable. This includes instances when our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject us to concentrations of risk consist principally of cash and cash equivalents and marketable debt securities.

Our cash and cash equivalents are held by one major financial institution in the U.S. and one in Korea.

Product candidates developed by us will require approvals or clearances from the U.S. Food and Drug Administration, or FDA, or international regulatory agencies prior to commercial sales. There can be no assurance that any of our product candidates will receive any of the required approvals or clearances. If we were to be denied approval or clearance or any such approval or clearance was to be delayed, it would have a material adverse impact on us.

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:

	<u>As of March 31,</u>	
	<u>2020</u>	<u>2019</u>
Outstanding options	4,506,950	4,506,950
Outstanding RSUs	1,102,528	821,936
Total	<u>5,609,478</u>	<u>5,328,886</u>

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

Recent Accounting Pronouncements

Application of New or Revised Accounting Standards – Adopted

In December 2019, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2019-12, *Simplifying the Accounting for Income Taxes*, or ASU 2019-12. The amendments in ASU 2019-12 include removing the exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income, or a gain, from other items (e.g., discontinued operations or other comprehensive income) and the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. ASU 2019-12 also amends other aspects of accounting for income taxes to help simplify and promote consistent application of U.S. GAAP. The guidance is effective for interim and annual periods beginning after December 15, 2020, with early adoption permitted. We early adopted ASU 2019-12 effective January 1, 2020, and it did not have a material impact on our consolidated financial statements. Although our adoption of ASU 2019-12 did not have a material impact on our consolidated financial statements during the first quarter of 2020, it may have a material impact on our consolidated financial statements in future periods due to the removal of the exceptions discussed above. The amendments related to intraperiod tax allocation were applied prospectively, and the amendment related to calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year will be applied prospectively.

Application of New or Revised Accounting Standards – Not Yet Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. The FASB subsequently issued amendments to ASU 2016-13, which have the same effective date and transition dates as described below. The new guidance supersedes existing U.S. GAAP for measuring and recording of credit losses on financial assets measured at amortized cost by replacing the incurred-loss model with an expected-loss model. Accordingly, these financial assets will be presented at the net amount expected to be collected. This new standard also requires that credit losses related to available-for-sale debt securities be recorded as an allowance through net income rather than reducing the carrying amount under the current, other-than-temporary-impairment model. For public business entities that meet the definition of a SEC filer, except entities that are eligible to be a smaller reporting company as defined by the SEC, the standard is effective for annual periods beginning after December 15, 2019, and interim periods therein. For all other entities, the standard is effective for annual periods beginning after December 15, 2022, and interim periods therein. Early adoption is permitted for all entities for annual periods beginning after December 15, 2018. With certain exceptions, adjustments are to be applied using a modified-retrospective approach by reflecting adjustments through a cumulative-effect impact on retained earnings as of the beginning of the fiscal year of adoption. We are currently evaluating the impact that this new standard and its related amendments will have on our consolidated financial statements and we have not yet determined when we will adopt this new standard.

Other recent authoritative guidance issued by the FASB (including technical corrections to the ASC), the American Institute of Certified Public Accountants, and the Securities and Exchange Commission during the three months ended March 31, 2020 did not, or are not expected to, have a material effect on our consolidated financial statements.

3. Financial Statement Details

Prepaid expenses and other current assets

As of March 31, 2020 and December 31, 2019, prepaid expenses and other current assets were made up of (in thousands):

	<u>March 31, 2020</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2019</u>
Prepaid preclinical and clinical trial services - with related party (Note 9)	\$ 1,249	\$ 1,021
Prepaid supplies - with related party (Note 9)	410	467
Prepaid rent	393	392
Insurance premium financing asset	381	757
Prepaid services	344	440
Prepaid insurance	288	372
Prepaid equipment maintenance	262	251
Interest receivable - marketable debt securities	205	222
Prepaid license fees	157	78
Due from related parties	114	47
Insurance claim receivables	29	34
Other	78	24
	<u>\$ 3,910</u>	<u>\$ 4,105</u>

Property, plant and equipment, net

As of March 31, 2020 and December 31, 2019, property, plant and equipment, net, was made up of (in thousands):

	<u>March 31, 2020</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2019</u>
Leasehold improvements	\$ 33,430	\$ 33,406
Buildings	22,690	22,690
Equipment	21,640	21,434
Software	1,195	1,195
Furniture & fixtures	408	383
	<u>79,363</u>	<u>79,108</u>
Accumulated depreciation	<u>(20,824)</u>	<u>(18,607)</u>
	<u>\$ 58,539</u>	<u>\$ 60,501</u>

Depreciation expense related to property, plant and equipment was \$2.2 million and \$1.8 million for the three months ended March 31, 2020 and 2019, respectively.

Other assets

As of March 31, 2020 and December 31, 2019, other assets were made up of (in thousands):

	<u>March 31, 2020</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2019</u>
Prepaid preclinical and clinical trial services - with related party (Note 9)	\$ 3,739	\$ 4,075
Restricted cash	179	179
Security deposit	113	113
Other	20	19
	<u>\$ 4,051</u>	<u>\$ 4,386</u>

Restricted cash is comprised of a certificate of deposit that serves as collateral for a letter of credit required by our landlord as a security deposit related to our facility in San Diego, California.

Accrued expenses

As of March 31, 2020 and December 31, 2019, accrued expenses were made up of (in thousands):

	<u>March 31, 2020</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2019</u>
Accrued bonus	\$ 2,611	\$ 2,002
Accrued compensation	1,631	1,064
Accrued professional and service fees	1,097	975
Accrued laboratory equipment, supplies and related services	559	640
Accrued preclinical and clinical trial costs	511	281
Accrued franchise, sales/use and property taxes	168	200
Other	57	181
	<u>\$ 6,634</u>	<u>\$ 5,343</u>

Other current liabilities

As of March 31, 2020 and December 31, 2019, other current liabilities were made up of (in thousands):

	<u>March 31, 2020</u> <u>(Unaudited)</u>	<u>December 31,</u> <u>2019</u>
Operating lease liability - current portion (including amounts with related parties, Note 9)	\$ 3,154	\$ 3,206
Financing obligation - current portion	381	757
Other	78	18
	<u>\$ 3,613</u>	<u>\$ 3,981</u>

Investment income, net

Net investment income is as follows for the three months ended March 31, 2020 and 2019 (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2020</u>	<u>2019</u>
	<u>(Unaudited)</u>	
Interest income	\$ 224	\$ 410
Investment amortization expense, net	(45)	(40)
Net realized losses on investments	(1)	—
	<u>\$ 178</u>	<u>\$ 370</u>

Interest income includes interest from marketable debt securities, notes receivable, other assets, and interest from bank deposits. We did not recognize an impairment loss on any investments during the three months ended March 31, 2020 and 2019.

4. Viracta Investment

In March 2017, we participated in a Series B convertible preferred stock financing and invested \$8.5 million in Viracta Therapeutics, Inc., or Viracta, a clinical stage drug development company. In May 2017, we executed an exclusive worldwide license with Viracta to develop and commercialize Viracta's proprietary histone deacetylase inhibitor drug candidate for use in combination with natural killer cell therapy and possibly additional therapies. At March 31, 2020, our investment in Viracta totaled \$9.3 million. Our investment in Viracta is reflected in equity investment on the condensed consolidated balance sheets.

In June 2018, Viracta executed a 2018 Note and Warrant Purchase Agreement with existing and new investors, including us. The initial closing under the Purchase Agreement occurred in June 2018, at which point we purchased a convertible note for \$0.4 million, which under certain circumstances was convertible into preferred stock of Viracta, and a warrant to purchase Viracta's common shares. The convertible note accrued interest at 8% and had a one-year maturity date. In September 2018, a milestone closing under the Purchase Agreement occurred, at which point we purchased an additional convertible note for \$0.4 million, which under certain circumstances was convertible into preferred stock of Viracta, and a warrant to purchase Viracta's common shares. The convertible note accrued interest at 8% and had a one-year maturity date. We classified the convertible notes as held-to-maturity notes receivable on the consolidated balance sheets. Effective January 31, 2019, the notes, together with accrued interest then outstanding, were converted to Series B preferred stock resulting in an increase to our investment in Viracta's Series B convertible preferred stock of \$0.8 million. In May 2019, we exercised warrants to acquire 253,120 shares of Viracta common stock. At December 31, 2019, our investment in Viracta totaled \$9.3 million.

Based on the level of equity investment at risk, Viracta is not a VIE and therefore is not consolidated under the VIE Model. In addition, we do not hold a controlling financial interest in Viracta and therefore we do not consolidate Viracta under the voting interest model. As the preferred stock is not considered in-substance common stock, the investment is not within the scope of accounting for the investment under the equity method. As the preferred stock does not have a readily determinable fair value and does not qualify for the practical expedient to estimate fair value in accordance with ASC 820, we have elected to apply the measurement alternative under ASC 321, pursuant to which we measure our investment in Viracta at cost, less impairment, adjusted for observable price changes in an orderly market for an identical or similar investment of the same issuer.

As of March 31, 2020, our qualitative impairment assessment did not indicate there were events or changes in circumstances that may have had a significant adverse effect on the fair value of the investment. We have not recorded any impairments as of March 31, 2020, or on a cumulative basis. Further, we have not identified any downward or upward adjustments due to observable price changes in the investment as of March 31, 2020, or on a cumulative basis.

5. Financial Instruments – Investments in Marketable Debt Securities

At March 31, 2020, our investments in available-for-sale debt securities are detailed below (in thousands):

	March 31, 2020			
	(Unaudited)			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Corporate debt securities	\$ 19,534	\$ —	\$ (30)	\$ 19,504
Foreign government bonds	1,001	—	—	1,001
Government sponsored securities	2,751	7	—	2,758
Current portion	23,286	7	(30)	23,263
Total	<u>\$ 23,286</u>	<u>\$ 7</u>	<u>\$ (30)</u>	<u>\$ 23,263</u>

As of March 31, 2020, the weighted-average remaining contractual life of our available-for-sale securities was approximately 0.2 years.

At December 31, 2019, our investments in available-for-sale debt securities are detailed below (in thousands):

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Current:				
Corporate debt securities	\$ 32,382	\$ 10	\$ (3)	\$ 32,389
Foreign government bonds	1,007	—	—	1,007
Government sponsored securities	2,752	—	(4)	2,748
Current portion	36,141	10	(7)	36,144
Noncurrent:				
Corporate debt securities	1,501	—	(4)	1,497
Noncurrent portion	1,501	—	(4)	1,497
Total	\$ 37,642	\$ 10	\$ (11)	\$ 37,641

Accumulated unrealized losses on debt securities classified as available-for-sale that have been in a continuous loss position for less than 12 months and for more than 12 months at March 31, 2020 and December 31, 2019 were as follows (in thousands):

	March 31, 2020 (Unaudited)			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate debt securities	\$ 19,504	\$ (30)	\$ —	\$ —
Total	\$ 19,504	\$ (30)	\$ —	\$ —

	December 31, 2019			
	Less than 12 months		More than 12 months	
	Estimated Fair Value	Gross Unrealized Losses	Estimated Fair Value	Gross Unrealized Losses
Corporate debt securities	\$ 11,021	\$ (3)	\$ 1,497	\$ (4)
Government sponsored securities	—	—	2,748	(4)
Total	\$ 11,021	\$ (3)	\$ 4,245	\$ (8)

At March 31, 2020, 23 of the securities were in an unrealized loss position. We evaluated our securities for other-than-temporary impairment and concluded that the decline in value was primarily caused by current economic and market conditions. We do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases. Therefore, we did not recognize any other-than-temporary impairment loss during the three months ended March 31, 2020.

Realized gains and losses on sales of available-for-sale debt securities during the three months ended March 31, 2020 and 2019 were immaterial.

6. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, based on our principal or, in absence of a principal, most advantageous market for the specific asset or liability.

We use a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires us to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value. The three tiers are defined as follows:

- Level 1— Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets at the measurement date. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment. Our Level 1 assets consist of bank deposits and money market funds.

- Level 2— Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities. Our Level 2 assets consist of corporate debt securities including commercial paper, government sponsored securities and corporate bonds, as well as foreign municipal securities.
- Level 3— Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

During the periods presented, no transfers were made into or out of the Level 1, 2 or 3 categories. We will continue to review the fair value inputs on quarterly basis.

We utilize a third-party pricing service to assist in obtaining fair value pricing for our investments in marketable debt securities. Inputs are documented in accordance with the fair value disclosure hierarchy.

Recurring Valuations

Financial assets and liabilities measured at fair value on a recurring basis are summarized below at March 31, 2020 and December 31, 2019 (in thousands):

	Fair Value Measurements at March 31, 2020			
	(Unaudited)			
	Total	Level 1	Level 2	Level 3
Assets:				
Current:				
Cash and cash equivalents	\$ 16,952	\$ 16,952	\$ —	\$ —
Corporate debt securities	19,504	—	19,504	—
Foreign government bonds	1,001	—	1,001	—
Government sponsored securities	2,758	—	2,758	—
Total assets measured at fair value	<u>\$ 40,215</u>	<u>\$ 16,952</u>	<u>\$ 23,263</u>	<u>\$ —</u>
	Fair Value Measurements at December 31, 2019			
	Total	Level 1	Level 2	Level 3
	Total	Level 1	Level 2	Level 3
Assets:				
Current:				
Cash and cash equivalents	\$ 15,508	\$ 15,508	\$ —	\$ —
Corporate debt securities	32,389	—	32,389	—
Foreign government bonds	1,007	—	1,007	—
Government sponsored securities	2,748	—	2,748	—
Noncurrent:				
Corporate debt securities	1,497	—	1,497	—
Total assets measured at fair value	<u>\$ 53,149</u>	<u>\$ 15,508</u>	<u>\$ 37,641</u>	<u>\$ —</u>

Non-recurring Valuations

Non-financial assets and liabilities are recognized at fair value subsequent to initial recognition when they are deemed to be other-than-temporarily impaired. There were no material non-financial assets and liabilities deemed to be other-than-temporarily impaired and measured at fair value on a non-recurring basis for the three months ended March 31, 2020.

7. Collaboration and License Agreements

Collaborative Arrangements

A collaborative arrangement is a contractual arrangement that involves a joint operating activity. These arrangements involve two or more parties who are (i) active participants in the activity, and (ii) exposed to significant risks and rewards dependent on the commercial success of the activity.

Cost Sharing Agreement

In January 2020, we entered into a Cost Allocation Agreement, or the Agreement, with ImmunityBio, Inc. and its subsidiaries, or ImmunityBio. The Agreement became effective on October 1, 2019. ImmunityBio is a related party, as it is an affiliate of NantWorks (Note 9). Under the Agreement and related work order, the parties agreed to conduct a joint study for the clinical research trial being conducted pursuant to the protocol titled QUILT 3.063: *A phase 2 study of combination therapy with an IL-15 superagonist (N-803), off-the-shelf CD16-targeted natural killer cells (haNK), and avelumab without cytotoxic chemotherapy in subjects with Merkel Cell Carcinoma (MCC) that has progressed on or after treatment with a checkpoint inhibitor*. The ImmunityBio study drug included in the joint study is ImmunityBio's proprietary IL-15 superagonist known as N-803 and our study drug is our proprietary "off-the-shelf" CD16-targeted natural killer cell therapy known as haNK.

We will act as the sponsor of this joint study for purposes of regulatory matters, including submissions, correspondence, and communications. Additionally, we are designated as the contracting party to execute agreements with third and related parties relating to the joint study. We and ImmunityBio will split certain joint study costs equally in accordance with the terms of the Agreement and related work order. Shared joint study costs include cost related to conducting the joint study development activities, such as personnel related costs, as well as all costs associated with regulatory matters. Costs and expenses incurred in connection with the development, manufacturing, supply, delivery, and pre-patient administration dosing mechanism of each party's study drug, are excluded from the shared joint study costs.

Under the Agreement, each of ImmunityBio and the company will receive exclusive rights to any new intellectual property developed that relates solely to its respective study drug, and the parties will have joint co-equal rights in any other intellectual property. The Agreement expires upon the second anniversary of the effective date with the option to renew for additional successive one-year terms, but work orders for any joint studies still in process at the time of termination will continue until the applicable study is completed.

During the three months ended March 31, 2020, we incurred \$0.1 million in costs related to the joint study that are subject to joint cost sharing under the Agreement which have been recorded as a reduction in research and development expense on the condensed consolidated statements of operations. At March 31, 2020, we have recorded a receivable of \$0.1 million from ImmunityBio related to ImmunityBio's share of joint study costs under the Agreement, which is included in prepaid and other current assets on the condensed consolidated balance sheets.

Exclusive Co-Development Agreement

In August 2016, we entered into an exclusive Co-Development Agreement, or the Co-Development Agreement, with Altor BioScience, LLC, or Altor. Altor is a related party, as it is a wholly owned subsidiary of ImmunityBio (Note 9). Under the Co-Development Agreement, the parties agreed to exclusively collaborate on the development of certain therapeutic applications combining our proprietary NK cells with Altor's N-801 and/or N-803 products with respect to certain technologies and intellectual property rights as may be agreed between the parties for the purpose of jointly developing therapeutic applications of certain effector cell lines.

We are the lead developer for each product developed by the parties pursuant to the Co-Development Agreement unless otherwise agreed to under a given project plan. Under the terms of the Co-Development Agreement, both parties granted a co-exclusive, royalty free, fully paid-up, worldwide license, with the right to sublicense (only to a third-party contractor assisting with research and development activities under this Co-Development Agreement and subject to prior consent, not to be unreasonably withheld), under the intellectual property, or IP, including the parties interest in the joint IP, solely to conduct any development activities agreed to by the steering committee as set forth in any development plan. Unless otherwise mutually agreed by the parties in the development plan for a project, we are responsible for all costs and expenses incurred by either party related to conducting clinical trials and other activities under each development program, including costs associated with patient enrollment, materials and supplies, third-party staffing and regulatory filings. Altor supplies free of charge, sufficient amounts of Altor products for all pre-clinical requirements and certain clinical requirements for up to 400 patients in phase I and/or phase II clinical trials, as required under the development plan for a project per the Co-Development Agreement.

Each company owns an undivided interest in and to all rights, title and interest in and to the joint product rights. The Co-Development Agreement expires upon the fifth anniversary of the effective date. We have dosed patients with N-803, an IL-15 superagonist, in several phase Ib/II trials. No charges for supplies by Altor were incurred in association with the above trials during the three months ended March 31, 2020 and 2019.

8. Commitments and Contingencies

Contingencies

We record accruals for loss contingencies to the extent that we conclude it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. We evaluate, on a quarterly basis, developments in legal proceedings and other matters that could cause a change in the potential amount of the liability recorded or of the range of potential losses disclosed. Additionally, we record our rights to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and when receipt is deemed probable. This includes instances where our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund.

Securities Litigation

In March 2016, a putative securities class action complaint captioned *Sudunagunta v. NantKwest, Inc., et al.*, No. 16-cv-01947 was filed in federal district court for the Central District of California related to the company's restatement of certain interim financial statements for the periods ended June 30, 2015 and September 30, 2015. A number of similar putative class actions were filed in federal and state court in California. The actions originally filed in state court were removed to federal court, and the various related actions were consolidated. Plaintiffs asserted causes of action for alleged violations of Sections 11 and 15 of the Securities Act of 1933 and Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. Plaintiffs sought unspecified damages, costs and attorneys' fees, and equitable/injunctive or other relief on behalf of putative classes of persons who purchased or acquired the company's securities during various time periods from July 28, 2015 through March 11, 2016. In September 2017, the court denied defendants' motion to dismiss the third amended consolidated complaint. On August 13, 2018, the district court granted plaintiffs' motions for class certification and to strike plaintiffs' claims under the Securities Exchange Act of 1934 and Rule 10b-5. On August 24, 2018, at the district court's direction, plaintiffs filed a fourth amended consolidated complaint. On August 27, 2018, defendants petitioned the U.S. Court of Appeals for the Ninth Circuit to authorize interlocutory appeal of the class certification order. On September 7, 2018, defendants answered the fourth amended consolidated complaint. On September 21, 2018, the parties informed the Ninth Circuit that they had reached a settlement in principle, and the parties moved to stay appellate proceedings. On September 24, 2018, the parties notified the district court that they had reached a settlement in principle. On November 9, 2018, the plaintiffs filed an unopposed motion for preliminary approval of the settlement and notice to class members. On January 9, 2019, the district court granted the motion for preliminary approval. A final approval hearing was held on April 29, 2019, and the district court granted final approval and entered judgment on May 31, 2019.

Under the terms of the settlement, we paid \$12.0 million to the plaintiffs as full and complete settlement of the litigation. We were responsible for \$1.2 million of the settlement amount, which was recognized in selling, general and administrative expense during 2018, while the remaining \$10.8 million was fully funded by our insurance carriers under our directors' and officers' insurance policy. We and the insurance carriers paid the settlement amount into a settlement fund in January 2019. Subsequent to receiving final approval of the settlement on May 13, 2019, the aforementioned settlement accrual, associated insurance claim receivable and restricted cash were released and are no longer reflected on the accompanying condensed consolidated balance sheets.

Stipulation of Settlement

In early April 2019, following board approval, which occurred in late March 2019, we entered into a settlement agreement, or the Stipulation of Settlement, with three stockholders of the company, each of whom had submitted a stockholder demand for the board to take action to remedy purported harm to the company resulting from certain alleged wrongful conduct concerning, among other things, disclosures about Dr. Soon-Shiong's compensation and a related-party lease agreement. The Stipulation of Settlement called for us to adopt certain governance changes, and for the three stockholders to file a stockholder derivative action in the Superior Court of the State of California, County of San Diego, followed by an application for court approval of the Stipulation of Settlement. On May 31, 2019, the court entered an order preliminarily approving the Stipulation of Settlement and scheduling the final settlement hearing for August 9, 2019. Pursuant to the Stipulation of Settlement, we have provided stockholders with notice of the settlement and the final settlement hearing.

Under the terms of the Stipulation of Settlement, which received final approval by the court on August 9, 2019, we paid an attorney's fee of \$0.5 million to the plaintiffs as part of the settlement. Of that amount, we were responsible for half, which was recognized in selling, general and administrative expense on the condensed consolidated statements of operations during the first quarter of 2019, while the other half was funded by our insurance carrier. We and the insurance carrier paid the settlement amount into a settlement fund in June 2019. Subsequent to receiving final approval of the settlement on August 9, 2019, the aforementioned settlement accrual, associated insurance claim receivable and restricted cash were released and are no longer reflected on the accompanying condensed consolidated balance sheets.

Insurance Recoveries

We have reflected our right to insurance recoveries, limited to the extent of incurred or probable losses, as a receivable when such recoveries have been agreed to with our third-party insurers and receipt is deemed probable. This includes instances where our third-party insurers have agreed to pay, on our behalf, certain legal defense costs and settlement amounts directly to applicable law firms and a settlement fund. The amount of such receivable recorded at March 31, 2020 and December 31, 2019 was \$30,000 and \$34,000, respectively, and is included in prepaid expenses and other current assets on our consolidated balance sheets.

Contractual Obligations - Leases

Substantially all of our operating lease right-of-use assets and operating lease liabilities relate to facilities leases. We lease: (i) a research facility and office space in San Diego, California; (ii) a research and manufacturing space in Culver City, California, from a related party; (iii) a research and manufacturing facility in El Segundo, California, also from a related party; (iv) a research facility in Torrance, California; and (v) a research facility in Woburn, Massachusetts. See Note 9 – *Related Party Agreements* for further information.

For the three months ended March 31, 2020 and 2019, \$1.3 million and \$1.2 million, respectively, including variable lease costs of \$0.3 million and \$0.2 million, respectively, was recorded in operating expenses on the condensed consolidated statements of operations. The weighted-average remaining lease term as of March 31, 2020 and December 31, 2019 was 4.3 years and 4.5 years, respectively. The weighted-average discount rate as of March 31, 2020 and December 31, 2019 was 9%. For the three months ended March 31, 2020 and 2019, cash outflows from operating leases, excluding variable lease costs, was \$1.0 million and \$1.3 million, respectively.

Future minimum lease payments at March 31, 2020 are presented in the following table (in thousands). Common area maintenance costs and taxes are not included in these payments.

Years ending December 31:	Operating Leases (a)
2020 (excluding the three months ended March 31, 2020)	\$ 3,221
2021	3,754
2022	3,671
2023	2,545
2024	1,083
Thereafter	1,730
Total future minimum lease payments	16,004
Less: Interest	2,671
Present value of operating lease liabilities	\$ 13,333

(a) Operating lease payments include \$3.3 million related to options to extend lease terms that are reasonably certain of being exercised.

In August 2018, NantBio, Inc., or NantBio, a related party (Note 9), assigned an agreement to us for the use of a third-party research facility, which provides us with the exclusive right to use and access to a portion of the third party's laboratory and vivarium premises. In conjunction with the assignment, we reimbursed NantBio for upfront payments which it had made to the third party of \$0.9 million, and paid \$0.5 million directly to the third party for an aggregate value of \$1.4 million. The assigned agreement is for a term of ten years and expires in June 2027. The agreement may be terminated by us at any time, with or without cause. In case of termination of the agreement, the third party will reimburse us for a pro-rata amount based upon the passage of time.

In September 2016, we entered into a lease agreement with 605 Doug St, LLC, a related party (Note 9), for approximately 24,250 square feet in El Segundo, California, which has been converted to a research and development laboratory and a current good manufacturing practice, or cGMP, manufacturing facility. The lease runs from July 2016 through July 2023. We have the option to extend the lease for an additional three year term through July 2026. The monthly rent is \$0.1 million with annual increases of 3% beginning in July 2017.

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 initial lease term runs for 48 months from April 29, 2016 through May 31, 2020. In June 2016, the lease was amended to add 260 square feet, for a total of 8,153 square feet. Base rent for the initial term of the lease is \$19,000 per month with a \$1 per square foot annual increase on each anniversary date. In August 2019, we exercised our right pursuant to the lease agreement to extend the term of the lease for an additional two years through May 31, 2022. Consequently, during the third quarter of 2019 we recognized an increase of \$0.6 million in both operating lease right-of-use assets and operating lease liabilities on the condensed consolidated balance sheets.

In November 2015, we entered into a facility license agreement with NantWorks LLC, or NantWorks, a related party (Note 9), for approximately 9,500 square feet of office space in Culver City, California, which has been converted to a research and development laboratory and a cGMP manufacturing facility. The license was effective in May 2015 and extends through December 2020. The monthly rent is \$47,000, with annual increases of 3% beginning in January 2017.

In June 2015, we entered into a lease agreement for an approximately 44,700 square foot facility in San Diego, California, for a research and development laboratory, related office and other related uses. The term of the lease extends for seven years commencing on August 1, 2016. The base rent is \$0.2 million per month with 3% annual increases on each anniversary date.

Commitments

We did not enter into any significant contracts during the three months ended March 31, 2020, other than those disclosed in these unaudited condensed consolidated financial statements.

9. Related Party Agreements

Our Chairman and CEO founded and has a controlling interest in NantWorks, which is a collection of multiple companies in the healthcare and technology space. As described below, we have entered into arrangements with NantWorks, and certain affiliates of NantWorks, to facilitate the development of new genetically modified NK cells for our product pipeline. Affiliates of NantWorks are also affiliates of the company due to the common control by and/or common ownership interest of our Chairman and CEO.

NantWorks

Under the NantWorks shared services agreement executed in November 2015, but effective August 2015, NantWorks provides corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy, and other support services. We are 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, 2020 and 2019, we recorded \$0.7 million and \$0.6 million, respectively, to selling, general and administrative expense, and \$0.5 million and \$0.3 million, respectively, to research and development expense under this arrangement on the condensed consolidated statements of operations. These amounts exclude certain general and administrative expenses provided by third party vendors directly for our benefit, which have been reimbursed to NantWorks based on those vendors' invoiced amounts without markup by NantWorks.

In June 2016, we amended the existing shared services agreement with NantWorks whereby we can provide support services to NantWorks and/or any of its affiliates. For the three months ended March 31, 2020 and 2019, we recorded expense reimbursements of \$0.3 million and \$0.2 million, respectively, to selling, general and administrative expense and \$0.5 million and \$0.5 million, respectively, to research and development expense.

We owed NantWorks a net amount of \$0.7 million and \$0.4 million for all agreements between the two affiliates at March 31, 2020 and December 31, 2019, respectively, which is included in due to related parties on the condensed consolidated balance sheets.

In November 2015, we entered into a facility license agreement with NantWorks, which became effective May 2015, for approximately 9,500 square feet in Culver City, California, which has been converted to a research and development laboratory and a cGMP manufacturing facility. Lease expense for this facility is recorded in research and development expense on the condensed consolidated statements of operations and was \$0.1 million for each of the three months ended March 31, 2020 and 2019.

Immuno-Oncology Clinic, Inc.

Beginning in 2017, we entered into multiple agreements with Immuno-Oncology Clinic, Inc., or the Clinic, to conduct various clinical trials. The Clinic was formerly known as John Lee, M.D. and Leonard Sender, M.D., Inc., a professional medical corporation, dba Chan Soon-Shiong Institutes for Medicine, in El Segundo, California. The Clinic is a related party as it is owned by one officer of NantKwest and NantWorks manages the administrative operations of the Clinic. Prior to June 30, 2019, one of the company's officers was an investigator or sub-investigator for all of the company's trials conducted at the Clinic.

In July 2019, we entered into a new agreement with the Clinic which superseded our existing agreements with the Clinic, effective as of July 1, 2019. The new agreement, as amended on March 31, 2020, covers clinical trial and research related activities on a non-exclusive basis relating to our existing clinical trials, commenced prior to July 1, 2019, and prospective clinical trials and research projects. The new agreement also specifies certain services and related costs that are excluded from the new agreement. Prior to commencing any work under the new agreement, the parties have agreed to execute written work orders setting forth the terms and conditions related to specific services to be performed, including financial terms. For existing clinical trials, commenced prior to July 1, 2019, fees incurred for services performed after July 1, 2019 are covered under the new agreement and applied towards the below-mentioned prepayments. The initial term of the new agreement is for one year, but the agreement allows for an automatic renewal and additional extensions beyond the initial term. In July 2019, we executed a clinical trial work order under the new agreement with the Clinic for an open-label, phase I study of PD-L1.t-haNK for infusion in subjects with locally advanced or metastatic solid cancers.

In consideration of the services to be performed under the new agreement, as amended on March 31, 2020, we agreed to make payments of up to \$7.5 million to the Clinic, of which \$3.75 million and \$1.875 million were paid in July 2019 and October 2019, respectively. As amended, a conditional payment of \$1.875 million shall be due and payable at such time, if any, that the payments made in July 2019 and October 2019 have been earned by the Clinic through performance of services. Under the term of the new agreement, the outstanding balance of our prepayment shall be increased on a quarterly basis by an interest credit computed in accordance with terms specified in the new agreement.

To the extent any portion of the prepayments remain unearned by the Clinic on the third anniversary of the new agreement, we may elect at our sole discretion either to (i) not extend the term of the new agreement and have the Clinic reimburse us for the total amount of any remaining unused portion of the prepayments, or (ii) extend the term of the new agreement for up to three additional one year periods, at which time the Clinic will reimburse us for the total amount of any remaining unused portion of the prepayments plus interest if reimbursement is not made within 60 days of expiration. The Clinic may terminate this agreement upon each anniversary date upon sixty (60) days prior written notice and reimbursement in full to us of any outstanding unearned balance of the prepayments, provided that any such termination by the Clinic will not apply with respect to any work orders still in effect at the time of such termination.

During the three months ended March 31, 2020 and 2019, \$0.1 million and \$0.4 million, respectively, has been recognized in research and development expense on the condensed consolidated statements of operations related to our agreements with the Clinic. At March 31, 2020 and December 31, 2019, we owed the Clinic \$0.1 million and \$0.1 million, respectively, for services excluded from the new agreement, which are included in due to related parties on the condensed consolidated balance sheets. At March 31, 2020 and December 31, 2019, we had a prepaid balance with the Clinic of \$5.0 million and \$5.1 million, respectively, which are included in prepaid expenses and other current assets, and other assets, on the condensed consolidated balance sheets. We anticipate that the remaining prepayment amount as of March 31, 2020 will be utilized in future periods as the Clinic provides additional services pursuant to the new agreement.

ImmunityBio

ImmunityBio, Inc., or ImmunityBio, is a related party, as it is an affiliate of NantWorks.

In January 2020, we entered into a cost sharing agreement with ImmunityBio as further described in Note 7 – *Collaboration and License Agreements*. During the three months ended March 31, 2020, we incurred \$0.1 million in costs related to the joint study being conducted that are subject to joint cost sharing under the Agreement which have been recorded as a reduction in research and development expense on the condensed consolidated statements of operations. At March 31, 2020, we have a receivable of \$0.1 million from ImmunityBio related to this agreement, which is included in prepaid expenses and other current assets on the condensed consolidated balance sheets.

In August 2016, we entered into an exclusive Co-Development Agreement with Altor as described in Note 7 – *Collaboration and License Agreements*. Altor is a related party as it is a wholly owned subsidiary of ImmunityBio. No charges for supplies by Altor were incurred in association with the trials during the three months ended March 31, 2020 and 2019.

In June 2015, we entered into a supply agreement with ImmunityBio pursuant to which we have the right to purchase ImmunityBio's proprietary bioreactors, made according to specifications mutually agreed to with ImmunityBio. We also have the right to purchase reagents and consumables associated with such equipment from ImmunityBio. When an upfront payment is made, it is included in prepaid expenses on the condensed consolidated balance sheets until the product is received. The agreement has an initial term of five years and renews automatically for successive one-year periods unless terminated earlier.

At each of March 31, 2020 and December 31, 2019, we had \$1.8 million in capitalized equipment purchased from ImmunityBio, which is included in property, plant and equipment, net, on the condensed consolidated balance sheets. During each of the three months ended March 31, 2020 and 2019, we recorded research and development expense associated with reagents and consumables purchased from ImmunityBio of \$0.1 million on the condensed consolidated statements of operations.

At March 31, 2020 and December 31, 2019 we had \$0.4 million and \$0.5 million, respectively, included in prepaid expenses and other current assets on the condensed consolidated balance sheets related to consumables purchased from ImmunityBio. At March 31, 2020 and December 31, 2019, no other balances were due between the parties.

605 Doug St. LLC

In September 2016, we entered into a lease agreement with 605 Doug St, LLC, an entity owned by our Chairman and CEO, for approximately 24,250 square feet in El Segundo, California, which has been converted to a research and development laboratory and a cGMP manufacturing facility. The lease runs from July 2016 through July 2023. We have the option to extend the lease for an additional three-year term through July 2026. The monthly rent is \$0.1 million with annual increases of 3% beginning in July 2017. Lease expense for this facility is recorded in research and development expense on the condensed consolidated statements of operations and was \$0.2 million for each of the three months ended March 31, 2020 and 2019, respectively. At March 31, 2020 and December 31, 2019, no balances were due between the parties.

NantBio

In August 2018, NantBio assigned an agreement to us for the use of a third-party research facility, which provides us with the exclusive right to use and access to a portion of the third party's laboratory and vivarium premises. NantBio is a related party, as it is an affiliate of NantWorks. In conjunction with the assignment, we reimbursed NantBio for upfront payments which it had made to the third party of \$0.9 million, and paid \$0.5 million directly to the third party for an aggregate value of \$1.4 million. The assigned agreement is for a term of ten years and expires in June 2027. The agreement may be terminated by us at any time, with or without cause. In case of termination of the agreement, the third party will reimburse us for a pro-rata amount based upon the passage of time.

At December 31, 2019, NantBio owed us \$8,400, which is included in prepaid expenses and other current assets on the condensed consolidated balance sheets. At March 31, 2020, no balances were due between the parties.

In March 2016, NantBio and the National Cancer Institute entered into a cooperative research and development agreement. The initial five year agreement covers NantBio and its affiliates, including us. Under the agreement, the parties are collaborating on the preclinical and clinical development of proprietary recombinant natural killer cells and monoclonal antibodies in monotherapy and in combination immunotherapies. We benefited from the preclinical and clinical research conducted during the first four years under this agreement. In each of April 2016, April 2017, August 2018 and May 2019, we paid \$0.6 million to the National Cancer Institute as a prepayment for services under the agreement. We recognize research and development expense related to this agreement ratably over a 12-month period for each funding year and recorded \$0.1 million and \$0.1 million of expense associated with the agreement in each of the three months ended March 31, 2020 and 2019. At March 31, 2020, we have accrued \$25,000 in anticipation of funding an additional \$0.6 million related to the fifth year of the agreement in April 2020. As of December 31, 2019, we had a balance of \$0.1 million included in prepaid expenses and other current assets related to this agreement, on the condensed consolidated balance sheets.

10. Stockholders' Equity

Stock Repurchase – In November 2015, the board of directors approved a share repurchase program, or 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 \$50.0 million of our outstanding shares of common stock, exclusive of any commissions, markups or expenses. The timing and amounts of any purchases were and will continue to 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. We have financed, and expect to continue to finance, the purchases with existing cash balances. At March 31, 2020, \$18.3 million remained authorized for repurchase under the 2015 Share Repurchase Program and no shares were repurchased during the three months ended March 31, 2020. The shares are formally retired through board approval upon repurchase.

11. Stock-Based Compensation

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

	Three Months Ended March 31,	
	2020	2019
	(Unaudited)	
Stock-based compensation expense:		
Employee stock options	\$ 105	\$ 997
Employee RSUs	290	250
Non-employee RSUs	50	104
	<u>\$ 445</u>	<u>\$ 1,351</u>
Stock-based compensation expense in operating expenses:		
Research and development	\$ 128	\$ 111
Selling, general and administrative	317	1,240
	<u>\$ 445</u>	<u>\$ 1,351</u>

Stock Options

The following table summarizes stock option activity under all equity incentive plans for the three months ended March 31, 2020:

	Number of Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value (in thousands)	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2019	4,506,950	\$ 9.37	\$ 5,710	5.8
Outstanding at March 31, 2020	<u>4,506,950</u>	\$ 9.37	\$ 3,085	5.6
Vested and Exercisable at March 31, 2020	<u>4,023,614</u>	\$ 10.13	\$ 3,085	5.3

The total unrecognized compensation cost related to non-vested stock options as of March 31, 2020 is \$1.0 million, which is expected to be recognized over a weighted-average period of 2.4 years.

During the three months ended March 31, 2019, we recognized proceeds of \$4.1 million from exercises of stock options by our Chairman and CEO. There were no option exercises during the three months ended March 31, 2020.

Restricted Stock Units

The following table summarizes the restricted stock units, or RSUs, activity under the 2015 Plan for the three months ended March 31, 2020:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested balance at December 31, 2019	1,139,428	\$ 2.23
Granted	33,500	\$ 6.43
Vested	(63,750)	\$ 5.90
Forfeited	(6,650)	\$ 2.71
Unvested balance at March 31, 2020	<u>1,102,528</u>	\$ 2.14

During the three months ended March 31, 2020, we granted 33,500 RSUs to employees. As of March 31, 2020, there was \$1.3 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted-average period of 2.0 years. Of that amount, \$1.2 million of unrecognized expense is related to employee grants with a remaining weighted-average period of 2.1 years and \$0.1 million of unrecognized expense is related to non-employee grants with a remaining weighted-average period of 0.6 years.

Warrants

During the three months ended March 31, 2019, we recognized proceeds of \$35.2 million upon the exercise of warrants by our Chairman and CEO. As of December 31, 2019 there were no warrants outstanding, and no warrants were issued during the three months ended March 31, 2020.

12. Income Taxes

The difference between the federal statutory tax rate of 21% and our 0% tax rate is due to losses in jurisdictions from which we cannot benefit.

Prior to the adoption of ASU 2019-12 in the first quarter of 2020, as described in Note 2, intraperiod tax allocation rules required us to allocate the provision for income taxes between continuing operations and other categories of earnings, such as other comprehensive income. In periods in which we had a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as other comprehensive income, we had to allocate the tax provision to the other categories of earnings. We then recorded a related tax benefit in continuing operations. However, with the adoption of ASU 2019-12, we are no longer required to allocate the tax provision to the other categories of earnings and related benefit to continuing operations under these circumstances.

We recorded unrealized gains on marketable debt securities during the three months ended March 31, 2019. As a result, we recorded a tax benefit of \$36,000 for the three months ended March 31, 2019 on the condensed consolidated statements of operations. We also recorded an increase to other comprehensive income of \$0.1 million for the three months ended March 31, 2019 on the condensed consolidated balance sheets.

We are operating in Korea. During the three months ended March 31, 2020 and 2019, there was no tax expense or benefit related to Korea.

We currently file federal and state income tax returns in the U.S. and in Korea. Income tax expense consists of U.S. federal, state, and Korean income taxes. To date, we have not been required to pay U.S. federal income taxes and only minimum state income taxes because of current and accumulated net operating losses.

On March 27, 2020, the U.S. enacted the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act. The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the U.S. economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which are expected to impact our financial statements include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. Consistent with previous years, we expect to continue to generate net losses in the foreseeable future. We currently have significant federal and state deferred tax assets attributed to prior net operating losses and research and experimentation tax credits. These deferred taxes are fully reserved. As we have never generated taxable income, the CARES Act feature allowing net operating losses originating in 2018, 2019 or 2020 to be carried back five years is not expected to have a significant impact. Management does not expect any other provisions of the CARES Act to have a material impact on our financial position, results of operations or cash flows during 2020.

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 Quarterly Report. This Quarterly Report 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 pioneer immunotherapy, harness the power of the innate immune system, implement precision cancer medicine and change the current paradigm of cancer care;
- any impact of the COVID-19 pandemic, or responses to the pandemic, on our business, clinical trials or personnel;
- 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, including that we eventually plan to advance therapies for virally induced infectious diseases;
- our beliefs regarding the success, cost and timing of our product candidate development activities and current and future clinical trials and studies, including study design;
- our expectations regarding our ability to utilize the phase I and II aNK and haNK clinical trials data to support the development of all of our product candidates, including our haNK, taNK and t-haNK product candidates;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses, including any planned investigational new drug, or 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, LLC, or NantWorks, 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 manufacturing facility and our belief that our manufacturing is capable of being conducted in-house;
- our belief in the potential of our aNK cells as a technology platform, and the fact that 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, haNK and t-haNK product candidates, will require significant additional clinical testing;

- even if we successfully develop and commercialize our aNK product candidate, we may not be successful in developing and commercializing our other product candidates either alone or in combination with other therapeutic agents;
- 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 future revenue, as well as our future operating expenses, 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 candidates and not infringe upon the intellectual property of others;
- regulatory developments in the United States, or U.S., and foreign countries; and
- our expectations regarding the period during which we qualify as an “emerging growth company” under the JOBS Act, and a “smaller reporting company,” as defined in Rule 12b-2 of the Securities Exchange Act of 1934.

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. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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 Quarterly Report 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 Quarterly Report.

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 Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect.

This Quarterly Report contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Quarterly Report, 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 Quarterly Report, “NantKwest,” “the company,” “we,” “us” and “our” refer to NantKwest, Inc. and its subsidiaries.

Overview

As a pioneering clinical-stage immunotherapy company, we are focused on harnessing the power of the innate immune system by using its natural killer cells, or NK cells, to treat cancer and viral infectious diseases. 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 co-activation by other support molecules, typically required to train and activate adaptive immune cells such as T-cells.

A critical aspect of our strategy is to invest significantly in innovating new therapeutic candidates, based upon our proprietary activated NK, or aNK, cell platform, and conducting clinical testing and scale manufacturing of our most promising biologic product candidates.

We hold the exclusive right to commercialize aNK cells, a commercially viable NK cell line, and a wide range of genetically modified derivatives capable of killing cancer and virally infected cells. We own corresponding United States, or U.S., and foreign composition and methods-of-use patents and applications covering the cells, improvements, methods of expansion and manufacture and use of aNK cells and their improvements as therapeutics to treat a spectrum of clinical conditions.

We also license exclusive commercial rights to a high-affinity CD16 receptor expressing enhancement of our aNK cell platform, covered in a portfolio of U.S. and foreign composition and methods-of-use patents and applications covering both the clinical use as a therapeutic to treat cancers in combination with antibody products, as well as the non-clinical use in laboratory testing of monoclonal antibodies.

We believe our proprietary NK cell platform, coupled with our integrated discovery ecosystem, positions us to implement precision cancer medicine by taking advantage of 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 cancer specific proteins. We believe proteins, selectively expressed on the cancer cells and not on the essential normal tissue, represent large untapped targeting opportunities for immune effector cell products derived from our aNK cell platform.

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.

Coronavirus Pandemic

In March 2020, the World Health Organization declared the novel coronavirus (SARS-CoV-2) a pandemic. In the same month, the President of the United States declared a State of National Emergency due to the COVID-19 outbreak. Many jurisdictions, particularly in North America (including the United States), Europe and Asia, as well as U.S. states in which we operate, including California, have adopted or are considering laws, rules, regulations or decrees intended to address the COVID-19 outbreak, including implementing travel restrictions, closing non-essential businesses and/or restricting daily activities. In addition, many communities have limited, and are considering to further limit, social mobility and gathering. Such restrictions and other impacts from COVID-19 may have an impact on our business.

Given the unprecedented and evolving nature of the pandemic, the future impact of these changes and potential changes on the company are unknown at this time. To date, we have seen no material adverse impact to our business from the COVID-19 pandemic. We anticipate, however, that enrollment of patients in our studies will likely take longer and that our clinical trials will require additional time to complete which will likely delay the timeline in which we were previously forecasting the commercialization of any of our product candidates and begin receiving revenue. During any such delays in our clinical trials, we will continue to incur fixed costs such as selling, general and administrative expenses and operating expenses related to our laboratory, GMP manufacturing, and office facilities.

Our office-based employees have been working from home since mid-March 2020, while ensuring essential staffing levels for our research and development operations remain in place, including maintaining key personnel in our laboratory and GMP manufacturing facilities. It is likely that the COVID-19 pandemic and resulting mitigation efforts will have an impact in the future on us or our third-party suppliers who manufacture laboratory supplies required for our in-house manufacturing process which in turn could have an impact on having sufficient clinical product supply available for our clinical trials.

There is significant uncertainty about the progression and ultimate impact of the pandemic on our business and operations. While COVID-19 did not materially impact our first quarter of 2020 results, we anticipate that COVID-19 could impact our business in the short-term due to factors such as fewer patients accessing treatment for cancer treatment.

Our Approach

Multiple Modes of aNK Directed Tumor Cell Killing. Our NK platform has demonstrated the ability to induce cell death in cancers and virally infected cells through a variety of concurrent mechanisms including:

- i. *Innate Killing*, whereby all of our NK platforms, aNK, haNK, taNK and t-haNK, recognize the abnormal proteins typically found on the surfaces of metabolically stressed cells, which upon binding, release toxic granules to immediately kill their targets;

- ii. *Antibody-Mediated Killing* with our haNK and t-haNK platforms, which are aNK cells engineered to express antibody receptors that can bind to therapeutically administered antibody products or to antibodies naturally produced in the body, thereby enhancing the cancer cell killing effects of those antibodies through Antibody Dependent Cellular Cytotoxicity, or ADCC; and
- iii. *CAR-Directed Killing* with our taNK and t-haNK platforms, which are aNK cells engineered to express chimeric antigen receptors, or CARs, that target tumor-specific proteins commonly found only on the surfaces of cancer cells and upon binding, induce cell death through the release of toxic granules directly into their targets and by the release of cytokines and chemokines, which recruit additional innate and adaptive immune responses, including the recruitment of cytotoxic T-cells.

All three modes of killing; *Innate Killing*, *Antibody-Mediated Killing*, and *CAR-Directed Killing*, are employed by our proprietary t-haNK platform, which combines all the enhanced NK killing functions of aNK, haNK and taNK into a single product platform.

Our primary target therapeutic area is cancer, with a heavy emphasis on solid tumors. According to the National Cancer Institute, there will be an estimated 1.8 million newly diagnosed cases of cancer in the U.S. in 2020. In 2019 there were an estimated 16.9 million people already living with cancer in the U.S. In addition, we plan to advance therapies for hematologic malignancies and virally induced infectious diseases.

Innate Killing - the aNK Platform. We have developed a unique NK cell platform, which we believe is capable of being manufactured as a cell-based “off-the-shelf” therapy that can be molecularly engineered in a variety of ways to boost its killing capabilities against cancers and virally infected cells. Unlike normal natural killer cells, our NK cells do not express the key inhibitory receptors that diseased cells often exploit to turn off the killing function of natural killer cells and escape elimination. We have developed a unique aNK cell, which omits key inhibitory receptors, while preserving critical activation receptors that enable selective innate targeting and killing of distressed and diseased cells. They do so through the recognition and binding of stress-proteins that are overexpressed on the surfaces of

- i. rapidly growing cancer cells due to oxidative and metabolic stress, nutrient deprivation and waste accumulation typical when cell growth outpaces the capacity of local circulation; and
- ii. virally infected cells where the cellular machinery is hijacked to produce an abundance of viral proteins and virions.

Our aNK cells can also deliver a more lethal blow to their target by delivering a larger payload of lytic enzymes and cytokines responsible for both direct and indirect killing when compared to other natural killer cells isolated from healthy donors. This is due to the higher density of lytic granules and larger cell volume possessed by aNK cells when compared to that of donor derived natural killer cells. We believe that our aNK cells can be produced at commercial scale as a ‘living drug’ using our proprietary manufacturing and distribution processes to adequately address select global cancer markets.

Several phase I safety studies with aNK cells have been conducted in a variety of bulky hematological cancers and solid tumors, enrolling 46 patients in a range of dose levels and schedules with encouraging evidence of single-agent activity and a durable remission, including complete responses in liquid tumors. Based on these earlier clinical trials, we have further modified our aNK platform through virus-free molecular engineering designed to leverage additional modes of killing available to aNKs, including antibody-mediated killing, the haNK platform, and both antibody-mediated and CAR-directed antigen targeted killing, the t-haNK platform.

Antibody-Mediated Killing - the haNK Platform. We have genetically engineered our aNK cell platform to overexpress high-affinity CD16 receptors, which bind to antibodies. These antibody-targeted haNK cells are designed to directly bind to IgG1-type antibodies, such as avelumab, trastuzumab, cetuximab and rituximab with the intention of enhancing the cancer killing efficacy of these antibodies by boosting the population of competent natural killer cells that can kill cancer cells through ADCC. Antibody products are abundantly utilized to treat cancer and it is estimated that they generate over \$100 billion in reported annual sales. A growing number of studies suggest that clinically meaningful responses to these antibody therapies correlate directly with the overall health of a patient's natural killer cell population and whether they express the high-affinity variant of the CD16 receptor. Currently available literature estimates that only approximately 10% to 15% of the addressable patient population eligible for antibody therapies carry high-affinity CD16 receptors. This implies that our haNK product candidate may have significant market potential as a combination therapy to potentially address a large number of patients who do not carry high-affinity CD16 receptors and, as a result, exhibit a poorer response to antibody therapies. We therefore intend to develop our haNK product candidate as a combination therapy with widely-used U.S. Food and Drug Administration, or FDA, approved antibody products such as avelumab, trastuzumab, cetuximab and rituximab. Current Good Manufacturing Practice, or cGMP, master and working cell banks of our haNK product candidate have been successfully established and will serve as our source for product for our clinical trials and commercialization going forward. We have optimized our haNK product manufacturing process partly through the successful development of a product that does not require IL-2 cytokine supplementation to the growth media every few days, thereby enabling us to overcome a technically challenging and costly limitation that many other natural killer cell-based therapies face. We have also successfully established processes for large-scale production, cryopreservation and long-term storage of final dose forms, thereby optimizing production efficiencies and allowing for on-demand availability with minimal handling at the infusion sites. Our cryopreserved haNK product has been approved for clinical testing in several phase Ib/II clinical trials, including our phase II Merkel cell cancer study.

CAR-Directed Killing - the taNK Platform. We have genetically engineered our aNK platform to express CARs that target tumor-specific antigens found on the surfaces of cancers and virally infected cells. Our taNK cells are designed to bind directly to these surface antigens and induce cell death through the release of toxic granules directly into the tumor cells and release cytokines and chemokines to recruit additional innate and adaptive immune responses, including the recruitment of cytotoxic T-cells. These tumor antigens encompass four categories of proteins, all of which can be targeted individually by our engineered taNK products:

- i. Checkpoint ligands, such as PD-L1 and B7-H4;
- ii. Well-established tumor proteins such as HER2 and CD19;
- iii. Novel surface antigens associated with cancer stem cells, such as CD123 and IGF-R1; and
- iv. Newly discovered proteins, or neoepitopes, from individual patient tumor samples.

Preclinical evidence has been mounting which demonstrates that taNK cell activation through the binding of its CAR receptors to these cancer specific proteins is potent enough to override many of the pre-existing inhibitory signals and immunosuppressive factors present in the tumor microenvironment that may be responsible for tumor resistance.

CAR-Directed and Antibody-Mediated Killing - the t-haNK Platform. Our newest and most promising platform for the development of therapeutic product candidates is an innovative, bioengineered combination of our haNK and taNK platforms that incorporates all the features of our haNK platform together with a CAR. The resulting line of products under this platform avails itself to all three modes of killing: *innate*, *antibody-mediated* and *CAR-directed killing*. These products also include one or more additional expression elements such as functional cytokines, chemokines and trafficking factors, making them amongst the most versatile in our portfolio. These products are intended to be combined with commercially available therapeutic antibodies to effectively target either two different epitopes of the same cancer specific protein or two entirely different cancer specific proteins. In addition to our two t-haNK product candidates, PD-L1.t-haNK, recently cleared to commence phase II testing, and CD19.t-haNK, authorized to commence phase I testing, a pipeline of prominent CARs for t-haNK, including HER2, which is nearing IND submission, and EGFR, which is advancing through human enabling studies, among others will enable us to address an even broader range of cancers as part of a chemotherapy-free combination regimen.

Research Update on our haNK Product Candidate. Our haNK cell therapeutic is a molecularly engineered variant of our aNK cell platform, which incorporates both the expression of

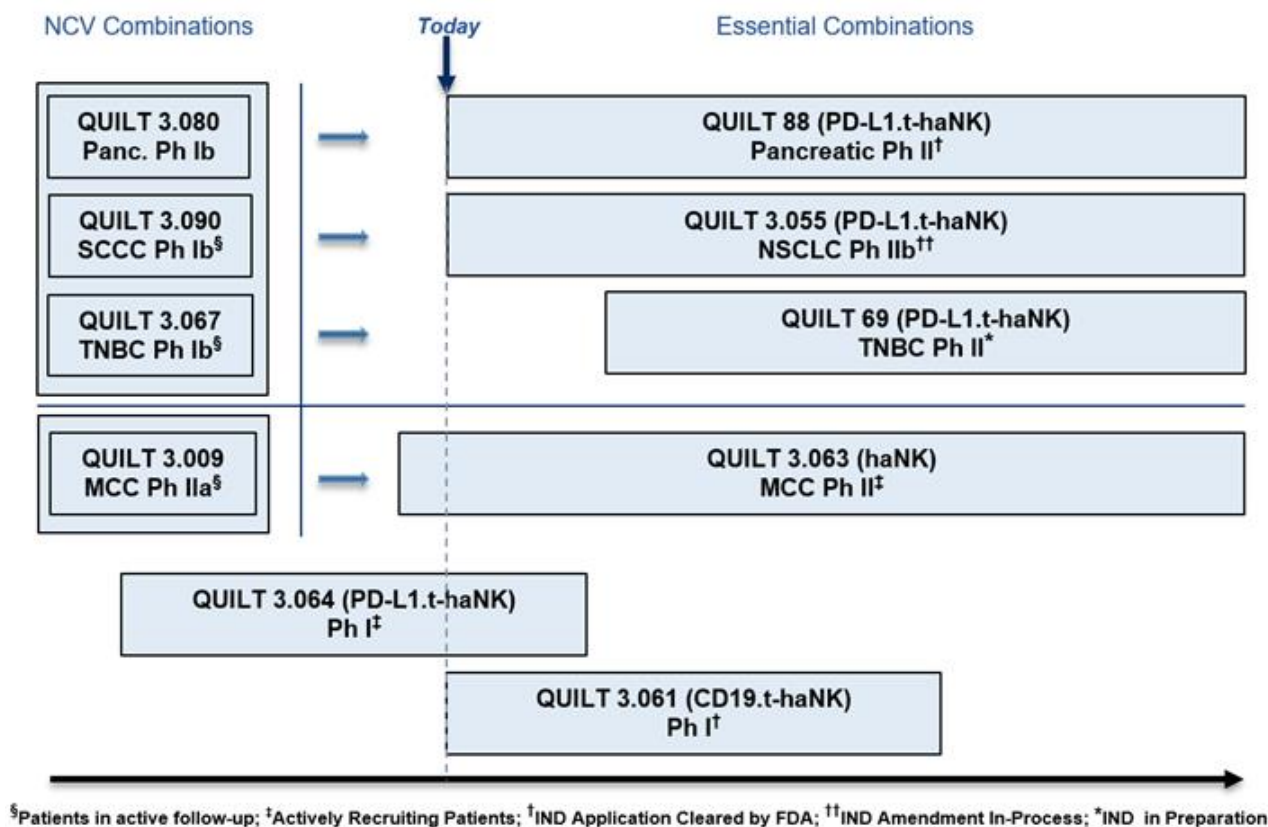
- i. A natural, high-affinity antibody engager, FcγRIIIa/CD16 receptor, which binds to therapeutically administered cancer-targeting antibodies, resulting in destruction of the cancer targets through a mechanism widely referred to as ADCC, and
- ii. The IL-2 support cytokine, whose expression is retained within the cell where it can exert its maximum effects of supporting growth and killing function while sparing leakage into the extracellular surroundings, where it could result in cytokine-related symptoms.

Newly published research by our collaborators at the National Cancer Institute under a NantKwest funded clinical research and development agreement¹ confirms and expands upon earlier research which demonstrates that irradiated and cryopreserved haNK cells maintain optimal performance under hypoxemic conditions, a marked distinction from healthy donor-derived natural killer cells, which exhibit significant impairment in both innate killing and antibody-mediated killing as well as in serial killing capabilities. NK performance under hypoxemic conditions is indicative of how natural killer cell therapies will fare within the tumor micro-environment. Key points include:

- i. Of the healthy donor natural killer cells tested, 92% exhibited a significant loss of innate lytic capability against cancer cell lines after exposure to 0% oxygen. In contrast, haNK cells maintained killing ability under the same hypoxic conditions.
- ii. Hypoxia led to decreases in antibody-mediated, or ADCC, killing by as much as 90% in healthy donor natural killer cells, whereas our haNK cells did not show diminished ADCC capacity under hypoxic conditions.
- iii. When combined with a human monoclonal antibody to mediate ADCC, killing by haNK cells was superior to that of healthy donor natural killer cells in all examined donors.
- iv. Healthy donor natural killer cells serial killing was significantly decreased under 0% oxygen. The addition of cetuximab increased serial killing by six-fold at 20% oxygen and 0% oxygen brought serial killing down to levels similar to those without cetuximab. Our haNK cells displayed a 24.6-fold increase in serial killing compared with healthy donor natural killer cells under 20% oxygen and this was not significantly decreased under 0% oxygen. The addition of cetuximab increased haNK cell serial killing 99-fold over healthy donor natural killer cells at 20% oxygen and likewise, was not significantly decreased under 0% oxygen.
- v. All findings were corroborated by corresponding RNAseq and proteomic analysis.

¹ Solocinski K, Padget MR, Fabian KP, et al. Overcoming hypoxia- induced functional suppression of NK cells. *J Immunother Cancer* 2020;8:e000246. doi:10.1136/jitc-2019-000246

Progressing NantKwest's Leading Clinical Programs



The IND application for QUILT 88 has recently been cleared by the FDA and multiple clinical sites are being opened. QUILT 88 is a phase II open-label, randomized, two-cohort comparative study of PD-L1.t-haNK, N-803 and aldoxorubicin in combination with standard-of-care therapy versus standard-of-care therapy alone for first-line maintenance and second line treatment of subjects with locally advanced or metastatic pancreatic cancer. The two cohorts include:

- First-line maintenance therapy in patients that have achieved either a partial response, complete response, or stable disease after first-line standard-of-care therapy; and
- Second or later-line therapy and within each cohort, enrolled subjects will be randomly assigned to receive PD-L1.t-haNK, N-803 and aldoxorubicin with standard-of-care in an experimental arm or standard-of-care only in the control arm.

The cohort for first-line maintenance will have three experimental arms, which allows for assessing individual agent attribution when adding PD-L1.t-haNK, N-803 and Aldoxorubicin to background therapy. Safety and progression-free survival will be compared between the group using Response Evaluation Criteria in Solid Tumors Version 1.1 based on Blinded Independent Central Review.

QUILT 3.055 is an ongoing study sponsored by our affiliate, ImmunityBio, for which an IND amendment is in process to incorporate a PD-L1.t-haNK treatment arm. We anticipate rapid adoption of this amendment at numerous clinical sites that have been active in enrolling patients under this protocol. QUILT 3.055 is a phase IIb, open-label study that will evaluate the combination of PD-L1.t-haNK, N-803 and a checkpoint inhibitor in subjects with non-small cell lung cancer that have confirmed disease progression by investigator assessment per Immune-related Response Evaluation Criteria in Solid Tumors, or irRECIST, during treatment on-study with N-803 and a checkpoint inhibitor. A second lung cancer trial, QUILT 59, is currently in preparation for IND filing with the FDA. QUILT 59 is a phase II/III open-label, randomized, three-cohort study of standard-of-care therapy in combination with PD-L1.t-haNK, N-803 and a checkpoint antibody versus standard-of-care chemotherapy alone for first and second line treatment of subjects with locally advanced or metastatic squamous and non-squamous non-small cell lung cancer.

Update on COVID-19 Related Clinical Activities. Regulatory clearance for two studies in distinct COVID-19 patient groups is anticipated during the second quarter of 2020, with enrollment planned at several area hospitals in Southern California:

- i. **QUILT-haNK-COVID-19.** Open-label, phase 1b study of the safety of haNK in combination with convalescent plasma, or CP, for treatment of high-risk, hospitalized adults with COVID-19. This clinical trial is designed to assess the safety and the immune enhancement activity of haNK alone and in combination with CP in hospitalized subjects with COVID-19. A total of thirty (30) subjects who have tested positive for SARS-CoV-2 and have confirmed COVID-19 lung disease that require supplemental oxygen, but not ventilator assistance, will be enrolled. Subjects may be receiving other supportive care in the hospitalized setting.
- ii. **QUILT-COVID-19-MSK.** Open-label, randomized phase 1b study of the safety of therapeutic treatment with immunomodulatory bone marrow-derived mesenchymal stem cells, or BM-Allo.MSC, in adults with severe COVID-19 infection. This clinical trial will evaluate the safety and efficacy of BM-Allo.MSC versus best supporting care in treating patients with severe disease requiring ventilator support during COVID-19 infection. A total of forty-five (45) subjects receiving care in the critical care or ICU setting for COVID-19 will be enrolled in this study. Subjects will be randomized in a 2:1 fashion to the experimental and control arms respectively.

To date, we have generated minimal revenue related to the non-clinical use of our cell lines and intellectual property. 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, 2020, we had an accumulated deficit of approximately \$680.6 million. Our net losses were \$18.4 million and \$17.9 million for the three months ended March 31, 2020 and 2019, respectively, and \$65.8 million and \$96.2 million for the years ended December 31, 2019 and 2018, respectively. Substantially all of our net losses resulted principally from stock-based compensation expense and costs incurred in connection with our ongoing clinical trials and operations, our research and development programs and from selling, general and administrative costs associated with our operations.

As of March 31, 2020 we had 153 employees. Personnel of related companies who provide corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy and other support services under our shared services agreement with NantWorks are not included in this number. For additional information, see Note 9 – *Related Party Agreements* of the “Notes to Unaudited Condensed Consolidated Financial Statements” included in Part I, Item I of this Quarterly Report. 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.

PD-L1.t-haNK Program

Our novel GMP-grade, cryopreserved, “off-the-shelf” bi-specific PD-L1.t-haNK NK cell therapy, which received authorization from the FDA in June 2019 to proceed with a first-in-human trial, has completed treatment for nine (9) patients across the first two dose cohorts of a phase I study in patients with locally advanced or metastatic solid cancers. We anticipate that this will prove to be safe to administer, based on past favorable safety profiles for other aNK cell products, and subsequently progress towards multiple phase II studies in patients with PD-L1 positive cancer indications. PD-L1.t-haNK is expected to serve as the backbone of a combination regimen that includes a therapeutic monoclonal antibody in addition to the IL-15 superagonist, N-803, through our exclusive co-development agreement with Altor, a related party (see Note 7 – *Collaboration and License Agreements*, of the “Notes to Unaudited Condensed Consolidated Financial Statements” included in Part I, Item I of this Quarterly Report). We believe that the addition of this selective IL-15 cytokine therapy will complement the efficacy of our bispecific NK cell therapy through its stimulation of the patient’s own resident population of natural killer and cytotoxic CD8 T-cells. A similar approach will be used for our CD19.t-haNK NK cell therapy in CD19 positive B-cell malignancies.

Viracta Investment

In March 2017, we participated in a Series B convertible preferred stock financing and invested \$8.5 million in Viracta Therapeutics, Inc., or Viracta, a clinical stage drug development company. In May 2017, we executed an exclusive worldwide license with Viracta to develop and commercialize Viracta’s proprietary histone deacetylase inhibitor drug candidate for use in combination with NK cell therapy and possibly additional therapies. At March 31, 2020, our investment in Viracta totaled \$9.3 million.

See Note 4 – *Viracta investment*, of the “Notes to Unaudited Condensed Consolidated Financial Statements” included in Part I, Item I of this Quarterly Report for a more detailed discussion regarding our investment in Viracta.

Collaboration Agreements

We anticipate that strategic collaborations will become an integral part of our operations, providing opportunities to leverage our partners’ expertise and capabilities to further expand the potential of our technologies and product candidates. We believe we are well positioned to become a leader in cell-based immunotherapy due to our broad and vertically integrated platform and through complementary strategic partnerships. We did not enter into any significant new collaboration agreements during the three months ended March 31, 2020, other than those discussed in this Quarterly Report.

In addition to the collaboration and license agreements discussed below, we may enter into a commercial agreement relating to an IL-15 superagonist product developed by an affiliate, and we are also pursuing supply arrangements for various investigational agents controlled by affiliates and third parties to be used in our clinical trials. These collaboration and supply agreements do not typically specify how sales will be apportioned between the parties upon successful commercialization of the product. As a result, we cannot guarantee that we will receive a percentage of the revenue that is at least proportional to the costs that we will incur in commercializing the product candidate. Furthermore, if Dr. Soon-Shiong was to cease his affiliation with us, ImmunityBio, or with NantWorks, these entities may be unwilling to continue these relationships with us on commercially reasonable terms, or at all, and as a result may impede our ability to control the supply chain for our combination therapies.

ImmunityBio, Inc. In January 2020, we entered into a Cost Allocation Agreement, or the Agreement, with ImmunityBio, Inc. and its subsidiaries, or ImmunityBio. The Agreement became effective on October 1, 2019. ImmunityBio is a related party, as it is an affiliate of NantWorks. Under the Agreement and related work order, the parties agreed to conduct a joint study for the clinical research trial being conducted pursuant to the protocol titled QUILT 3.063: *A phase 2 study of combination therapy with an IL-15 superagonist (N-803), off-the-shelf CD16-targeted natural killer cells (haNK), and avelumab without cytotoxic chemotherapy in subjects with Merkel Cell Carcinoma (MCC) that has progressed on or after treatment with a checkpoint inhibitor.* The ImmunityBio study drug included in the joint study is ImmunityBio’s proprietary IL-15 superagonist known as N-803 and our study drug is our proprietary “off-the-shelf” CD16-targeted natural killer cell therapy known as haNK.

We will act as the sponsor of this joint study for purposes of regulatory matters, including submissions, correspondence, and communications. Additionally, we are designated as the contracting party to execute agreements with third and related parties relating to the joint study under Work Order Number One. We and ImmunityBio will split certain joint study costs equally related to Work Order Number One, in accordance with the terms of the Agreement. Shared joint study costs include cost related to conducting the joint study development activities, such as personnel related costs, as well as all costs associated with regulatory matters. Costs and expenses incurred in connection with the development, manufacturing, supply, delivery, and pre-patient administration dosing mechanism of each party's study drug, are excluded from the shared joint study costs. To date, there has been minimal joint research activity under the Agreement and as of March 31, 2020 we have incurred \$0.1 million of costs that are subject to joint cost sharing under the Agreement which have been recorded as a reduction in research and development expense on the condensed consolidated statements of operations.

Under the Agreement, each of ImmunityBio and the company will receive exclusive rights to any new intellectual property developed that relates solely to its respective study drug, and the parties will have joint co-equal rights in any other intellectual property. The Agreement expires upon the second anniversary of the effective date with the option to renew for additional successive one-year terms, but work orders for any joint studies still in process at the time of termination will continue until the applicable study is completed.

See Note 7 – *Collaboration and License Agreements*, of the “Notes to Unaudited Condensed Consolidated Financial Statements” included in Part I, Item I of this Quarterly Report for a more detailed discussion regarding our collaboration and license agreements.

Agreements with Related Parties

Our Chairman and CEO, Dr. Soon-Shiong, founded and has a controlling interest in NantWorks, which is a collection of multiple companies in the healthcare and technology space. We have entered into arrangements with NantWorks, and certain affiliates of NantWorks that, taken together, we expect will facilitate the development of new genetically modified NK cells for our product pipeline. Affiliates of NantWorks are also affiliates of the company due to the common control by and/or common ownership interest of our Chairman and CEO.

See Note 9 – *Related Party Agreements*, of the “Notes to Unaudited Condensed Consolidated Financial Statements” included in Part I, Item 1 of this Quarterly Report for a more detailed discussion regarding our related party agreements.

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. To date, we have generated minimal revenue related to the non-clinical use of our cell lines and intellectual property. We have no products approved for commercial sale and 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 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 our product candidates through clinical development, including the conduct of our ongoing and any future 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 as discussed in greater detail in Part II, Item 1A, “*Risk Factors*” of this Quarterly Report.

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.

We expect that our selling, general and administrative expenses during the year ended December 31, 2020 will increase as compared to the year ended December 31, 2019. 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, future funding efforts, corporate governance, internal controls, investor relations, disclosure and similar requirements applicable to public companies. Additionally, if and when we believe that a regulatory approval of a 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 debt securities, sublease rental income, interest expense from the accretion of our financing obligations, and foreign currency income (expense).

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 primarily relates to minimum income taxes in the State of California. Our income tax benefit to date relates primarily to the amortization of deferred tax liabilities at our Korean subsidiary.

Results of Operations

Comparison of the three months ended March 31, 2020 and 2019

	<u>Three Months Ended March 31,</u>		<u>\$ Change</u>	<u>% Change</u>
	<u>2020</u>	<u>2019</u>		
	<u>(Unaudited, \$ in thousands)</u>			
Revenue	\$ 21	\$ 5	\$ 16	320%
Operating expenses:				
Research and development (including amounts with related parties)	13,234	12,598	636	5%
Selling, general and administrative (including amounts with related parties)	5,373	5,742	(369)	(6%)
Total operating expenses	<u>18,607</u>	<u>18,340</u>	<u>267</u>	<u>1%</u>
Loss from operations	<u>(18,586)</u>	<u>(18,335)</u>	<u>(251)</u>	<u>1%</u>
Other income (expense):				
Investment income, net	178	370	(192)	(52%)
Interest expense	(7)	(3)	(4)	133%
Other income, net (including amounts with related parties)	32	47	(15)	(32%)
Total other income	<u>203</u>	<u>414</u>	<u>(211)</u>	<u>(51%)</u>
Loss before income taxes	<u>(18,383)</u>	<u>(17,921)</u>	<u>(462)</u>	<u>3%</u>
Income tax benefit	<u>—</u>	<u>36</u>	<u>(36)</u>	<u>(100%)</u>
Net loss	<u>\$ (18,383)</u>	<u>\$ (17,885)</u>	<u>\$ (498)</u>	<u>3%</u>

Research and Development

Research and development expense increased \$0.6 million during the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. The increase in research and development expense was primarily attributable to increases of \$0.5 million related to third-party facility and manufacturing process validation and qualification costs related to our El Segundo cGMP facility and an increase of \$0.4 million related to depreciation expense mainly driven by equipment placed in service at our El Segundo manufacturing facility. In addition, research and development expense increased by \$0.2 million due to an increase in fees for shared services rendered under our shared services agreement with NantWorks as a result of more clinical trial support activities from shared services personnel, \$0.2 million for pre-clinical trial costs mainly driven by a third-party agreement, \$0.2 million in higher cell bank costs, driven primarily by increased activity, and \$0.1 million related to increased property taxes. These increases in research and development expense were offset in part by a \$0.6 million decrease in amortization expense due to the underlying asset being fully amortized as of March 2019 and decreases in external clinical trial costs of \$0.4 million with our clinical trial sites driven by decreased activity.

We expect our research and development expenses to increase significantly for the foreseeable future as we advance our product candidates through clinical development and conduct our ongoing and planned clinical trials.

Selling, General and Administrative

Selling, general and administrative expense decreased \$0.4 million during the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. The decrease in selling, general and administrative expense was primarily attributable to decreases of \$0.9 million in stock-based compensation expense, driven by the completion of executive stock-based compensation vesting in March 2019, and lower travel related expenses of \$0.2 million due to less activity. These decreases in selling, general and administrative expense were offset in part by an increase in legal expenses of \$0.3 million primarily due to higher contracting, trademark, and patent related expenses, higher insurance expenses of \$0.2 million which was driven by increases in directors and officers insurance, and higher consulting expenses of \$0.2 million.

Other Income

Other income decreased by \$0.2 million during the three months ended March 31, 2020, as compared to the three months ended March 31, 2019. The decrease in other income was due primarily to lower investment income, as we had lower average marketable-debt securities balances held during the three months ended March 31, 2020, as compared to the year ago period.

Liquidity and Capital Resources

Sources of Liquidity

Our principal sources of liquidity are our existing cash, cash equivalents, and marketable debt securities. We have historically invested our cash primarily in investment grade short- to intermediate-term corporate debt securities, commercial paper, government sponsored securities, U.S. treasury securities, and foreign government bonds and classify these investments as available-for-sale. Certain of these investments are subject to general credit, liquidity and other market risks. The general condition of the financial markets and the economy may increase those risks and may affect the value and liquidity of investments and restrict our ability to access the capital markets. During the three months ended March 31, 2019, our Chairman and CEO exercised warrants and options resulting in proceeds to us of \$35.2 million and \$4.1 million, respectively.

As of March 31, 2020, we had cash and cash equivalents, and restricted cash of \$17.1 million as compared to \$15.7 million as of December 31, 2019. The increase was attributable to cash flows provided by investing activities of \$14.2 million, offset in part by cash used in operating and financing activities of \$12.6 million and \$0.1 million, respectively.

Investments in marketable debt securities were \$23.3 million as of March 31, 2020, all of which were short-term investments, as compared to \$80.5 million as of March 31, 2019, of which \$76.3 million were short-term investments.

Cash Flows

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

	Three Months Ended March 31,	
	2020	2019
	(Unaudited, in thousands)	
Cash used in (provided by):		
Operating activities	\$ (12,596)	\$ (13,078)
Investing activities	14,163	(19,459)
Financing activities	(123)	39,195
Net increase in cash, cash equivalents, and restricted cash	<u>\$ 1,444</u>	<u>\$ 6,658</u>

Operating Activities

For the three months ended March 31, 2020, our net cash used in operating activities of \$12.6 million consisted of a net loss of \$18.4 million, partially offset by \$3.4 million in adjustments for non-cash items, and \$2.4 million of cash provided by net working capital changes. Adjustments for non-cash items primarily consisted of \$2.2 million in depreciation and amortization, \$0.7 million of amortization of operating lease right-of-use assets, \$0.4 million in stock compensation expense, and \$0.1 million related to other non-cash items. Changes in net working capital consisted primarily of increases from accounts payable of \$1.3 million, accrued expenses of \$1.0 million, other assets of \$0.3 million, due to related party of \$0.3 million, and prepaid and other current assets of \$0.2 million, partially offset by a decrease in operating lease liabilities of \$0.8 million.

For the three months ended March 31, 2019, our net cash used in operating activities of \$13.1 million consisted of a net loss of \$17.9 million, partially offset by \$4.3 million in adjustments for non-cash items, and \$0.5 million of cash provided by net working capital changes. Adjustments for non-cash items primarily consisted of \$2.4 million in depreciation and amortization, \$1.4 million in stock compensation expense, and \$0.6 million of amortization of operating lease right-of-use assets, reduced by \$0.1 million in non-cash interest. Changes in net working capital consisted primarily of increases in accrued expenses of \$0.8 million, accounts payable of \$0.7 million, and prepaid, other current assets, and other assets of \$0.1 million, partially offset by decreases in operating lease liabilities of \$0.7 million, operating lease right-of-use assets of \$0.2 million, and due to related party of \$0.2 million.

Investing Activities

For the three months ended March 31, 2020, net cash provided by investing activities was \$14.2 million, which was primarily attributable to \$24.6 million in sales and maturities of marketable debt securities, partially offset by \$10.3 million in purchases of marketable debt securities, and \$0.1 million in purchases of property, plant and equipment.

For the three months ended March 31, 2019, net cash used in investing activities was \$19.5 million, which was primarily attributable to \$50.3 million in purchases of marketable debt securities, and \$2.1 million in purchases of property, plant and equipment, partially offset by \$32.9 million in sales and/or maturities of marketable debt securities. During the first quarter of 2019 our purchases of marketable debt securities was driven by \$39.2 million of cash proceeds received in March 2019 from the exercise of stock options and warrants, together with reinvestment of excess cash related to maturing securities. Our investments in property, plant and equipment during the first quarter of 2019 mainly related to our El Segundo, California, facilities.

Financing Activities

For the three months ended March 31, 2020, net cash used in financing activities was \$0.1 million, which related primarily to net share settlement of vested RSUs for payment of employee payroll taxes.

For the three months ended March 31, 2019, net cash provided by financing activities was \$39.2 million, which related primarily to cash proceeds of \$35.2 million and \$4.1 million resulting from the exercise of warrants and stock options, respectively, by our Chairman and CEO during March 2019.

Future Funding Requirements

To date, we have generated minimal revenue related to the non-clinical use of our cell lines and intellectual property, and we have no products approved for commercial sale and 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 as well as costs related to future fundraising efforts. 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 our existing cash, cash equivalents, and marketable debt securities, and our ability to borrow from affiliated entities, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months following the issuance date of the financial statements based on our Chairman and CEO's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required. 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 impacts of COVID-19 on our operations;
- the costs of manufacturing, distributing and processing our product candidates;
- the number and characteristics of any other product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements including our arrangements with ImmunityBio and its subsidiaries and Viracta;
- 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 or the company.

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 and Commitments

During the three months ended March 31, 2020, 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, 2019.

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 Security and Exchange Commission rules.

Critical Accounting Policies and Significant Judgments and Estimates

In the notes to our audited consolidated financial statements and in “*Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations*” included in our 2019 Annual Report on Form 10-K, we have disclosed those accounting policies that we consider to be significant in determining our results of operations and financial condition. Except as noted below, there have been no other material changes to those policies that we consider to be significant since the filing of our 2019 Annual Report on Form 10-K. The accounting principles used in preparing our unaudited condensed consolidated financial statements conform in all material respects to U.S. GAAP.

The preparation of condensed consolidated financial statements in conformity with U.S. GAAP 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, we evaluate our estimates, including those related to valuation of equity-based awards, deferred income taxes and related valuation allowances, preclinical and clinical trial accruals, impairment assessments, useful lives of long-lived assets, loss contingencies, and fair value measurements. We base our estimates on historical experience and on various other market-specific and relevant assumptions that we believe to be reasonable under the circumstances. Estimates are assessed each period and updated to reflect current information, such as the economic considerations related to the impact that the recent coronavirus disease (COVID-19) could have on our significant accounting estimates. Actual results could differ from those estimates.

Recently Adopted Accounting Policies

Refer to Note 2 – *Summary of Significant Accounting Policies*, of the “Notes to Unaudited Condensed Consolidated Financial Statements” included in Part I, Item 1 of this Quarterly Report for a discussion of recent accounting pronouncements or changes in accounting pronouncements that are of significance, or potential significance, to us.

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 2019 Annual Report on Form 10-K. At March 31, 2020, there have been no material changes to the financial market risks described at December 31, 2019. 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 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 CEO and CFO, 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.

Management, with the participation of our CEO and CFO, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2020. The term “disclosure controls and procedures,” as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our CEO and CFO, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2020, our CEO and CFO have concluded that, as of March 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended March 31, 2020 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 claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

ITEM 1A. RISK FACTORS.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as other information included in our 2019 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.

Any risk factors that have changed since our Annual Report on Form 10-K will be noted with an asterisk ().*

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 related to the non-clinical use of our cell lines and intellectual property, 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, 2020, we had an accumulated deficit of approximately \$680.6 million. We incurred net losses of \$18.4 million and \$17.9 million for the three months ended March 31, 2020 and 2019, 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 haNK, taNK and t-haNK platforms 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 U.S. Food and Drug Administration, or FDA, approval, commercializing our products. We will also incur costs as we hire additional personnel and increase our manufacturing capabilities, including the lease or purchase of a facility for the manufacturing of our product candidates for our ongoing and any future 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. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

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 revenue 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 and maintain profitability depends significantly on our success in many areas, including:

- our research and development efforts, including preclinical studies and clinical trials of our haNK, taNK and t-haNK platforms and our product candidates;
- continuing to develop 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 Practices, or cGMP, manufacturing facilities and processes to support clinical development and meet the market demand for product candidates that we develop, if approved;
- addressing any competing technological and industry developments;
- identifying, assessing, acquiring and/or developing new technology platforms and product candidates across numerous therapeutic areas;
- establishing and maintaining relationships with contract research organizations, or CROs, and clinical sites for the clinical development, both in the U.S. and internationally, of our product candidates;
- successful and timely completion of preclinical and clinical development of our product candidates and any other future product candidates;
- obtaining regulatory approvals and marketing authorizations for product candidates, including a continued acceptable safety profile both prior to and following any marketing approval of our product candidates;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- launching and commercializing any approved products, either directly or with a collaborator or distributor, including the development of a commercial infrastructure;
- obtaining market acceptance of and acceptable reimbursement for any approved products;
- identifying, assessing and developing new product candidates;
- 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;
- defending against third-party interference or infringement claims, if any;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of our product candidates is eventually 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 additional 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, virally infectious diseases, and other diseases requires substantial amounts of capital. We will also require a significant additional amount of capital to commercialize any approved products.

As of March 31, 2020, we had cash and cash equivalents of \$17.0 million and marketable debt securities of \$23.3 million. We are using and expect to continue to use our existing cash and cash equivalents and marketable debt securities to fund expenses in connection with our ongoing and any future clinical trials, our manufacturing facilities and processes and the hiring of additional personnel, and for other research and development activities, working capital and general corporate purposes, including our share repurchase program. We believe that our existing cash, cash equivalents, and investments in marketable debt securities, and our ability to borrow from affiliated entities, will be sufficient to fund our operations for at least the next 12 months following the issuance date of the financial statements based upon our Chairman and CEO's intent and ability to support our operations with additional funds, including loans from affiliated entities, as required. Our estimate as to how long we expect our existing cash and cash equivalents to be available to fund our operations is based on assumptions that may be proved inaccurate, and we could deplete our available capital resources sooner than we currently expect. In addition, 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 than we anticipate if we choose to expand more rapidly than we presently anticipate.

Our future capital requirements may depend on, and could increase significantly as a result of, 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 and any products for which we receive regulatory approval;
- the number and characteristics of any other product candidates we develop or acquire;
- our ability to establish and maintain strategic collaborations, licensing or other commercialization arrangements and the terms and timing of such arrangements, including our arrangements with ImmunityBio and its subsidiaries and Viracta;
- 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 costs related to commercializing product candidates independently;
- 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 or the company.

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 our common stockholders' rights. 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, or be unable to continue or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations and cause the price of our common stock to decline.

****Our business may be adversely affected by outbreaks of epidemic, pandemic or contagious diseases, including the recent coronavirus disease (COVID-19) outbreak.***

Outbreaks of epidemic, pandemic or contagious diseases, such as COVID-19, may significantly disrupt our operations and adversely affect our business, financial condition and results of operations. In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic as the novel coronavirus continues to spread throughout the world. The spread of this pandemic has caused significant volatility and uncertainty in the U.S. and international markets and has resulted in increased risks to our operations. We are monitoring a number of risks related to this pandemic, including the following:

- **Supply Chain:** While to date we have not experienced significant disruptions in our supply chain and distribution, an extended duration of this pandemic could result in disruptions in the future. For example, quarantines, shelter-in-place and similar government orders, travel restrictions and health impacts of the COVID-19 pandemic, could impact the availability or productivity of personnel at third-party laboratory supply manufacturers, distributors, freight carriers and other necessary components of our supply chain. In addition, there may be unfavorable changes in the availability or cost of raw materials, intermediates and other materials necessary for production, which may result in disruptions in our supply chain and adversely affect our ability to manufacture and distribute certain product candidates for clinical supply.
- **Clinical Trials:** This pandemic has not significantly affected us during the first quarter of 2020, however, it is likely to adversely affect certain of our clinical trials, including our ability to initiate and complete our clinical trials within the anticipated timelines. Due to site and participant availability during the pandemic, new subject enrollment is expected to slow in the short-term for most of our clinical trials. For ongoing trials, we have seen an increasing number of clinical trial sites imposing restrictions on patient visits to limit risks of possible COVID-19 exposure, and we may experience issues with participant compliance with clinical trial protocols as a result of quarantines, travel restrictions and interruptions to healthcare services. The current pressures on medical systems and the prioritization of healthcare resources toward the COVID-19 pandemic have also resulted in interruptions in data collection and submissions for certain clinical trials and delayed starts for certain planned studies. As a result, our anticipated filing and marketing timelines may be adversely impacted.
- **Overall economic and capital markets decline:** The impact of the COVID-19 pandemic could result in a prolonged recession or depression in the U.S. or globally that could harm the banking system, limit demand for all products and services and cause other seen and unforeseen events and circumstances, all of which could negatively impact us. The continued spread of COVID-19 has led to and could continue to lead to severe disruption and volatility in the U.S. and global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets in the future. In addition, trading prices on the public stock market, including our common stock, have been highly volatile as a result of the COVID-19 pandemic.
- **Regulatory Reviews:** The operations of the U.S. Food and Drug Administration, or FDA, or other regulatory agencies may be adversely affected. In response to COVID-19, federal, state and local governments are issuing new rules, regulations, orders and advisories on a regular basis. These government actions can impact us, our members and our suppliers. There is also the possibility that we may experience delays with obtaining approvals for our Investigational New Drug, or IND, applications.
- **Financial:** While to date, the financial impact to our business has not been material, we anticipate that the pandemic could have an adverse financial impact in the short-term and potentially beyond. As a result of slower patient enrollment, we may not be able to complete our clinical trials as planned or in a timely manner. We expect to continue spending on research and development in the second quarter of 2020 and beyond, and we could also have unexpected expenses related to the pandemic. The short-term continued expenses, as well as the overall uncertainty and disruption caused by the pandemic, will likely cause a delay in our ability to commercialize a product and adversely impact our financial results.

The foregoing risks may have an adverse effect on our overall business, financial condition and results of operations. Additionally, the ongoing COVID-19 pandemic may also affect our operating and financial results in a manner that is not presently known to us or that we currently have not considered as significant risks to our operations. This pandemic may also amplify many of the other risks described throughout the “Risk Factors” section of this Quarterly Report. Any resulting financial impact cannot be reasonably estimated at this time. The extent to which the COVID-19 pandemic impacts our business and results will depend on future developments, which are uncertain and cannot be predicted with confidence, including the duration and scope of the outbreak, any potential future waves of the pandemic, new information which may emerge concerning the severity of COVID-19 and the ongoing and future actions to contain it or treat its impact, among others.

We may use our financial and human resources to pursue a particular type of treatment, or treatment for a particular type of cancer, and fail to capitalize on programs or treatment of other types of cancer that may be more profitable or for which there is a greater likelihood of success.

Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of cancer, and may forego or delay pursuit of opportunities with other programs, investigational medicines, or treatment for other types of cancer, which could later prove to have greater commercial potential. Moreover, given the rapidly evolving competitive landscape and the time it takes to advance a product through clinical development, an incorrect decision to pursue a particular type of treatment or cancer may have a material adverse effect on our results of operation and negatively impact our future clinical strategies. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs for investigational medicines or clinical trials may not yield any commercially viable products. If we do not accurately evaluate and anticipate the commercial potential or target market for a particular type of treatment or cancer, we may choose to spend our limited resources on a particular treatment, or treatment for a particular type of cancer, and then later learn that another type of treatment or cancer that we previously decided not to pursue would have been more advantageous.

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.

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 product candidates derived thereof, including genetically modified haNK, taNK and t-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 for one or more product candidates derived from it, and then successfully commercialize our product candidates addressing numerous therapeutic areas. Our aNK platform and our haNK, taNK and t-haNK product candidates are in varying 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 haNK, taNK and t-haNK 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 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;
- training a sufficient number of medical personnel how to properly administer 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 viral associated infectious diseases; 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 in order for us to successfully develop, commercialize and manufacture our product candidates utilizing haNK, taNK and t-haNK cells.

****Even if we successfully develop and commercialize our haNK 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.***

We believe that our ability to realize the full value of our aNK platform will depend on our ability to successfully develop and commercialize haNK and our other product candidates in a wider range of indications. We are simultaneously pursuing preclinical and clinical development of a number of product candidates spanning several types of cancers. For example, we are devoting substantial resources toward the development of haNK and t-haNK product candidates as combination therapies with commercially approved monoclonal antibodies and late-stage product candidates for solid tumors such as breast, pancreatic, lung, head and neck and hematologic malignancies such as diffuse large B-cell lymphoma, or DLBCL, and serious viral diseases such as COVID-19.

Even if we are successful in continuing to build our pipeline of product candidates based on our technology platform, obtaining regulatory approvals and commercializing any approved product candidates will require substantial additional funding beyond our existing cash and cash equivalents and marketable debt securities, 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 assure you that we will be able to successfully advance any product candidates through the development process. Our research programs may initially show promise in identifying product candidates, but ultimately fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- our 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 U.S. for any of our product candidates, we may be required to have an allowed IND for each product candidate. As of the date of this filing, we have numerous INDs for clinical trials that have been authorized in the U.S. We 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 platform products prove successful, we might not be able to remain competitive because of the rapid pace of technological development in the biopharmaceutical field. Our haNK, taNK and t-haNK product candidates will compete with other cell and molecule-based immunotherapy approaches using and/or targeting natural killer cells, T-cells and dendritic cells.

Competitors focused on CAR-T related treatment approaches include AbbVie Inc., Atara Biotherapeutics, Inc., Intrexon Corporation, Allogene Therapeutics, Inc., Bristol-Myers Squibb Company, JW Therapeutics Co., Ltd., Amgen, Inc., Leucid Bio Ltd., Bellicum Pharmaceuticals, Inc., Medisix Therapeutics Pte Ltd., Bluebird Bio, Inc., Mesoblast Ltd., Calibr/Scripps Research, Mustang Bio, Inc., CARsgen Therapeutics, Nanjing Legend Biotechnology Co., Ltd, Cartherics Pty Ltd, Novartis AG, Pfizer, Inc., Cellectis SA, Poseida Therapeutics, Inc., Celularity, Inc., Servier Laboratories, Celyad SA, Takeda/Shire, Fortress Biotech, Inc., TC BioPharm Ltd., Gilead Sciences, Inc., Transposagen Biopharmaceuticals, Inc., Humanigen, Inc., Unum Therapeutics, Inc., Immune Therapeutics, Inc., and Xyphos, Inc.

Competitor companies focused on other T-cell based approaches include Adaptimmune Ltd., Adicet Bio, Inc., Autolus Therapeutics, plc, Cell Medica Limited, GlaxoSmithKline plc., Green Cross LabCell Corp., Immunocore Limited, Iovance Biotherapeutics, Inc., Kiadis Pharma Netherlands B.V., Lion TCR Pte Ltd., MolMed, S.p.A., Precision Biosciences, Inc., Janssen Pharmaceuticals, Inc., Noile-Immune Biotech, Inc., Anixa Biosciences, Inc., Beam Therapeutics Inc., BioNTech SE, Cartesian Therapeutics, Inc., and Takara Bio, Inc.

Competitor companies focused on dendritic cell based approaches include Argos Therapeutics, Inc., Biovest International, Inc., ImmunoCellular Therapeutics, Ltd., Merck & Co, Inc./Immune Design, Inc., Inovio Pharmaceuticals, Inc., Intrexon Corporation, Medigene AG, and Northwest Biotherapeutics, Inc.

Competitor companies focused on natural killer cell based approaches include Kiadis Pharma Netherlands B.V./CytoSen Therapeutics, Inc., Dragonfly Therapeutics, Inc., Fate Therapeutics, Inc., Gamida Cell, Ltd., Nkarta Therapeutics, Inc., Onkimmune Ltd., NKMax America, Artiva Biotherapeutics, HebeCell Corp., Vycellix, Inc., oNKo-innate Pty Ltd., and Ziopharm Oncology, Inc.

Competitor companies focused on large molecule immunotherapy approaches include Cytomx Therapeutics, Inc., Innate Pharma SA, and Sorrento Therapeutics, Inc. Other potential immunotherapy competitors include Affimed GmbH, Agios Pharmaceuticals, Inc., Codiak Biosciences, Glycostem Therapeutics BV, Triumvira Immunologics, Century Therapeutics, Incusys Therapeutics, Inc., GammaDelta Therapeutics Ltd., Lyell Immunopharma, Inc., and GT Biopharma, Inc.

There are currently two approved T-cell based treatments which are marketed by Novartis AG and Gilead Sciences/Kite Pharma. There is currently one approved dendritic cell-based cancer vaccine which is marketed by Dendron Pharmaceuticals, LLC for the treatment of metastatic castration resistant prostate cancer.

Many of our current or potential 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. Many of these companies also have more experience in conducting clinical trials, obtaining FDA and other regulatory approvals, and manufacturing, marketing and distributing therapeutic products. Smaller or clinical-stage companies like us may successfully compete by establishing collaborative relationships with larger pharmaceutical companies or academic institutions. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of cancer and other diseases, which could give such products significant regulatory and market timing advantages over any of our product candidates. 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, which could result in our competitors establishing a strong market position before we are able to enter the market. 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. We may not be successful in marketing any product candidates we may develop against competitors.

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.

While we are free to pursue all antibodies, we are reliant on third parties and affiliates for such antibodies on which to base our taNK, haNK and t-haNK product candidates. We do not know if we can obtain such antibodies from third parties on commercially reasonable terms and such reliance on third parties may delay our development and increase the associated development costs.

We have also entered into collaborations with affiliates of NantWorks to provide us with access to their database of genomic, transcriptomic and proteomic information collected from a broad array of tumor cell and peripheral blood 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. We cannot assure you that using our technology in combination with theirs 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 and haNK phase I and II clinical trials 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. The results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidate.***

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 product candidates 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 and II clinical trial data for aNK, haNK, and t-haNK observed to date to support our planned clinical trials for all of our product candidates, including our haNK and t-haNK product candidates. To date, we have several INDs for our haNK and t-haNK product candidates, and we cannot offer assurances that the FDA will allow us to utilize the phase I and II aNK and haNK data to support other planned clinical trials or allow our anticipated INDs for (i) planned phase I or phase Ib/IIa clinical trials for our other product candidates, (ii) planned phase IIb/III clinical trials for our haNK and t-haNK product candidates as potential combination therapies, or (iii) any other planned clinical trials, including registration studies.

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 authorization, 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 Contract Research Organizations, or 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 that our third-party contractors and clinical investigators comply with clinical trial protocols, comply with regulatory requirements, or meet their obligations to us in a timely manner;
- 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 Good Clinical Practices, or 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.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential.

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 U.S. 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 may contract;
- for clinical trials conducted by the Immuno-Oncology Clinic, Inc., or the Clinic, a related party, the FDA or other regulatory authorities could view our study results as potentially biased even if we achieve such clinical trial endpoints; 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 provide any assurance 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.

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, haNK and t-haNK platforms are uncertain and may never be realized.***

Our NK platforms are in the early stages of development. The company currently has multiple ongoing clinical trials to evaluate cryopreserved haNK and t-haNK cells in company sponsored clinical trials. 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 NK cells that meet our minimum specifications. In addition, our haNK product candidate has only been tested in a small number of patients. Results from these clinical trials may not necessarily be indicative of the safety and tolerability or efficacy of our products as we expand into larger clinical trials.

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 platform product candidates 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 platform product candidates are safe. We do not have data on possible harmful long-term effects of aNK platform product candidates 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 platform therapy is uncertain and is subject to significant risk.

****We have limited experience as a company conducting clinical trials and have relied and will rely on third parties and related parties to conduct many of our preclinical studies and clinical trials. Any failure by a third party, related party, or by us to conduct the clinical trials according to Good Clinical Practices 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, the only company sponsored studies to engage in patient enrollment have been for the following indications: Merkel cell, pancreatic, squamous head and neck, non-small cell lung, triple negative breast, AML, colorectal and advanced solid tumor. Our relative lack of experience conducting clinical trials may contribute to our planned clinical trials not beginning or completing on time, if at all. In addition, we have entered into an agreement with the Clinic, a related party, to continue to conduct and oversee certain of our clinical trials. 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, the Clinic, and other third parties must communicate and coordinate with one another in order for our trials to be successful. Additionally, our CROs, the Clinic, and other third parties may also have relationships with other commercial entities, some of which may compete with us. If our CROs, the Clinic, 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, the Clinic, 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 GMP and Good Tissue Practice, or GTP, 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, the Clinic, 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, haNK, taNK and t-haNK platforms 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.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. In addition, some of our trials are being run by the Clinic, which is controlled by one of our employees. Under certain circumstances, the company may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between the company, the Clinic and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

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, even if only temporary, could harm our business.

If we lose members of our senior management for a short or an extended time, 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 CEO and our principal stockholder, and Barry Simon, our President and Chief Administrative Officer. Although Dr. Soon-Shiong focuses heavily 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 ImmunityBio and NantWorks, which is a collection of multiple companies in the healthcare and technology space. The risks related to our dependence upon Dr. Soon-Shiong are particularly acute given his ownership percentage, the commercial and other relationships that we have with entities affiliated with him, role in our company and reputation. If we were to lose Drs. Soon-Shiong or Simon for a short or an extended time, for any reason, including the contraction of COVID-19, 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.

Competition for qualified personnel in the biotechnology and pharmaceuticals industry is intense due to the limited number of individuals who possess the skills and experience required. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options, warrants, and restricted stock units that vest over time. Additionally, we provided warrants that vested upon the achievement of certain performance milestones to Dr. Soon-Shiong. These performance warrants provided to Dr. Soon-Shiong were exercised in full in March 2019. The value to employees of stock options, warrants, and restricted stock units 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. We may not be able to attract and retain quality personnel on acceptable terms, or at all, which may cause our business and operating results to suffer.

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

Our Chairman and CEO, Dr. Soon-Shiong, is the founder of NantWorks. The various NantWorks companies are currently exploring opportunities in the immunotherapy, infectious disease and inflammatory disease fields. In particular, we have agreements with a number of related parties that provide services, technology and equipment for use in our efforts to develop our product pipeline. Dr. Soon-Shiong holds a controlling interest, either directly or indirectly, in these entities. Consequently, 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. In addition, 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 other therapeutic fields which we may target in the future). 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.

We are also pursuing supply arrangements for various investigational agents controlled by affiliates to be used in our clinical trials. If Dr. Soon-Shiong was to cease his affiliation with us, ImmunityBio, or with NantWorks, these entities may be unwilling to continue these relationships with us on commercially reasonable terms, or at all, and as a result may impede our ability to control the supply chain for our combination therapies. These collaboration agreements do not typically specify how sales will be apportioned between the parties upon successful commercialization of the product. As a result, we cannot guarantee that we will receive a percentage of the revenue that is at least proportional to the costs that we will incur in commercializing the product candidate.

Furthermore, in November 2015, we entered into a Shared Services Agreement with NantWorks, pursuant to which NantWorks and/or any of its affiliates provides corporate, general and administrative, manufacturing strategy, research and development, regulatory and clinical trial strategy, and other support services to us and our subsidiaries. If Dr. Soon-Shiong was to cease his affiliation with us or with NantWorks, we may be unable to establish or maintain this relationship with NantWorks on a commercially reasonable basis, if at all. As a result, we could experience a lack of business continuity due to loss of historical and institutional knowledge and a lack of familiarity of new employees and/or new service providers with business processes, operating requirements, policies and procedures, and we may incur additional costs as new employees and/or service providers gain necessary experience, particularly in connection with issues or concerns we may have as a public company. In addition, the loss of the services of NantWorks might significantly delay or prevent the development of our products or achievement of other business objectives by diverting management's attention to transition matters and identification of suitable replacements, if any, and could have a material adverse effect on our business and results of operations.

****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 add other management, accounting, regulatory, manufacturing and scientific staff. As of March 31, 2020, we had 153 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 may need to hire additional accounting and other personnel and augment our infrastructure as a result of 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 haNK, taNK or t-haNK cells on a large scale or in a cost-effective manner.***

haNK, taNK and t-haNK cells have been grown in various quantities in closed cell culture systems and intermediate to larger-scale bioreactors. With all manufacturing efforts being conducted in-house, we will need to develop the ability to grow haNK, taNK and t-haNK cells on a large-scale basis in a cost efficient manner. While we have made great strides with our haNK production, including a validated cryopreserved form of the product, we have not demonstrated the ability to manufacture these cells beyond quantities sufficient for our clinical programs. We have not demonstrated the ability to manufacture our taNK and t-haNK cells beyond quantities sufficient for research and development and limited clinical activities. We have also experienced increases in manufacturing costs and sporadic decreases in manufacturing yield of haNK, taNK and t-haNK cells. In addition, we have no experience manufacturing our NK cells specifically at the capacity that will be necessary to support commercial sales. The novel nature of our technology also increases the complexity and risk in the manufacturing process. In 2017, we opened our Culver City, California, site for the manufacture of cryopreserved haNK cells for our planned clinical trials and finished the build-out of our larger El Segundo, California, site in 2018 for the manufacture of our haNK, taNK and t-haNK cells for our 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 haNK, taNK and t-haNK cells manufactured in the new facility to our 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 to grow and produce our cells. Reliance on such third-party suppliers exposes us to supply interruptions and shortages that could have an adverse effect on our ability to produce product. Moreover, our present production process may not meet our initial expectations as to reproducibility, yield, purity or other measurements of performance. Any supply interruption from third parties and entities that are affiliated with Dr. Soon-Shiong and/or NantWorks could materially harm our ability to manufacture our product candidates until a new source of supply, if any, could be identified and qualified. We may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. 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 haNK, taNK and t-haNK cells on a large scale or in a cost-effective manner.

aNK platform cells have been produced at academic institutions associated with our other clinical trial sites. In the past, the lack of production of aNK platform cells has caused delays in the commencement of our clinical trials. We have been establishing NK cell production capacity to meet anticipated demand for our planned clinical trials but may not be able to successfully build out our capacity to meet our current and anticipated future needs. Any damage to or destruction of our facility and equipment, prolonged power outage, contamination or shut down by the FDA or other regulatory authority could significantly impair or curtail our ability to produce haNK, taNK and t-haNK cells.

We are dependent on third parties to store our aNK, haNK, taNK and t-haNK cells, and any damage or loss to our master cell bank would cause delays in replacement, and our business could suffer.

The aNK cells of our master and working cell banks are stored in freezers at a third party biorepository and also stored in our freezers at our production facility. If these cells are damaged at both facilities, including by the loss or malfunction of these freezers or our back-up power systems, as well as by damage from fire, power loss or other natural disasters, we would need to establish replacement master and working cell banks, which would impact clinical supply and delay our patients' treatments. If we are unable to establish replacement cell banks, 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 that we may use do not maintain high standards of manufacturing, our ability to develop and commercialize haNK, taNK or t-haNK 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 we may use in the future to produce our products do not pass a pre-approval inspection, the FDA will not grant market approval for haNK, taNK or t-haNK 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 haNK, taNK or t-haNK cell therapies 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 haNK, taNK or t-haNK cells. If our component part manufacturers and suppliers fail to provide components of sufficient quality, that meet our required specifications, our clinical trials or commercialization of haNK, taNK or t-haNK cells could be delayed or halted, and we could face product liability claims.

If we or any of our third-party manufacturers that we may engage 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 that we may use in the future. We and any of our third party manufacturers that we may engage are subject to federal, state and local laws and regulations in the U.S. 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 taNK and t-haNK cells, which we believe will be required for the storage and distribution of our taNK and t-haNK product candidates.

We have not demonstrated that taNK and t-haNK 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 form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze taNK and t-haNK 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 taNK and t-haNK 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 haNK, taNK or t-haNK cells on a large scale or in a cost-effective manner.

We rely on third party healthcare professionals to administer haNK, taNK or t-haNK cells to patients, and our business could be harmed if these third parties administer these cells incorrectly.

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

In addition, if we achieve the ability to freeze and thaw our taNK and t-haNK cells, third party medical personnel will have to be trained on proper methodology for thawing haNK, taNK or t-haNK 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 intend to provide training materials and other resources to these third-party medical personnel, the thawing of haNK, taNK or t-haNK cells will occur outside our supervision and may not be administered properly. If, due to a third-party error, people believe that haNK, taNK or t-haNK cells are ineffective or harmful, the desire to use haNK, taNK or t-haNK 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, if approved for commercial sale, 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;

- the ability to offer appropriate patient access programs, such as co-pay assistance;
- the extent to which physicians recommend our products to their patients;
- 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 haNK, taNK and t-haNK 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 haNK, taNK and t-haNK cells gain acceptance, the markets for treatment of patients with our target indications may not be as significant as we estimate.

Even if we are able to commercialize any product candidates, such products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which would harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay the commercial launch of the product and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates we may develop obtain marketing approval.

Our ability to successfully commercialize any products that we may develop also will depend in part on the extent to which reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Government authorities also impose mandatory discounts for certain patient groups and may seek to increase such discounts at any time. Future regulation may negatively impact the price of our products, if approved. It may be difficult to promptly obtain coverage and profitable payment rates from both the government-funded and private payors for any of our approved product candidates, and this may have a material adverse effect on our operating results, our ability to raise capital and our overall financial condition.

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 haNK, taNK and t-haNK 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 haNK, taNK and t-haNK cells are processed and administered may increase our exposure to liability. Medical personnel administer haNK, taNK and t-haNK 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, haNK, taNK and t-haNK cells or components of our haNK, taNK and t-haNK cell therapy may cause unforeseen harmful side effects. For example, a patient receiving haNK, taNK and/or t-haNK cells could have a severe allergic reaction or could develop an autoimmune condition to materials infused with the haNK, taNK and/or t-haNK cells.

In addition, we have not conducted studies on the long-term effects associated with the media that we use to grow our haNK, taNK and t-haNK cells. Similarly, we expect to use media in freezing our haNK, taNK and t-haNK cells for shipment. These media could contain substances that have proved harmful if used in certain quantities. As we continue to develop our haNK, taNK and t-haNK 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 haNK, taNK and t-haNK 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;
- a potential decrease in our share price; 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 obtained 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 an 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 and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize any product in the U.S. 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 U.S. 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 U.S.;
- 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 U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- the impact of public health epidemics on the global economy, such as the coronavirus pandemic currently having an impact throughout the world; 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. For example, we entered into an agreement whereby Viracta granted to us exclusive world-wide rights to Viracta's phase II drug candidate, VRx-3996, for use in combination with our platform of NK cell therapies. However, if Viracta fails to raise sufficient capital to complete their pivotal phase II trial, if their trial is unsuccessful, or if our future clinical trial of NK cell therapy in combination with VRx-3996 fails, the value of the Viracta license would be materially adversely affected.

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, ongoing 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 affiliated entities and 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 have a material adverse effect on our business.

We expect that these risks and exposures related to our internal computer systems will remain high for the foreseeable future due to the rapidly evolving nature and sophistication of cyber threats to our internal computer systems. There can be no assurance that our efforts to implement adequate security measures will remain sufficient to protect the company against future cyber-attacks. 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, suffer damage to our reputation, the further development and commercialization of our product candidates could be delayed and our stock price could decline.

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, or in conjunction with, 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 may 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, pandemics, epidemics, or other business interruption, including the recent novel strain of coronavirus (SARS-CoV-2) that originally surfaced in Wuhan, China in December 2019. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain SARS-CoV-2 or treat its impact, among others. If any disaster were to occur, our ability to operate our clinical trials could be seriously, or potentially completely, impaired. 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.

****A coronavirus pandemic is ongoing in many parts of the world and may result in significant disruptions to our clinical trials, preclinical studies and supply chain which could have a material adverse effect on our business.***

A coronavirus pandemic exists as of the filing of this report. As the pandemic is still evolving as of this time, much of its impact remains unknown, and it is impossible to predict the impact it may have on the development of our business.

The coronavirus pandemic may result in significant delays or disruptions in our clinical trials, which could affect or delay the regulatory approval process of our product candidates. If the patients involved with these clinical trials become infected with the coronavirus disease, we may have more adverse events and deaths in our clinical trials as a result. We may also face difficulties enrolling patients in our clinical trials if the patient populations that are eligible for our clinical trials are impacted by the coronavirus pandemic.

Additionally, if our clinical trial patients are unable to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from the coronavirus pandemic, we may experience higher drop-out rates or delays in our clinical trials.

The severity of the coronavirus pandemic could also make access to our existing supply chain difficult or impossible by delaying the delivery of key raw materials used in our product candidates and therefore delay the delivery of such products for use in our clinical trials. Any of these results could materially impact our business and have an adverse effect on our business.

Our employees, affiliates, independent contractors, clinical investigators, CROs, data safety and monitoring boards, 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, misconduct or other illegal activity by our employees, affiliates, independent contractors, clinical investigators, CROs, data safety and monitoring boards, 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 U.S. 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 U.S., 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 U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional U.S. 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 U.S. 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 U.S. 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 European Union, or 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 biosimilar products exist in the U.S., 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 natural killer cell-based immunotherapy has been approved to date. Public perception may be influenced by claims, such as claims that cell-based immunotherapy is unsafe, unethical, or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to cell-based immunotherapy in general could result in greater government regulation and stricter labeling requirements of cell-based immunotherapy products, including any of our product candidates, and could cause a decrease in the demand for any products we may develop. Adverse public attitudes may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, 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.

Our business may be materially affected by changes to fiscal and tax policies. Negative or unexpected tax consequences could adversely affect our results of operations.

The Tax Cuts and Jobs Act of 2017 was approved by Congress on December 20, 2017. This legislation significantly changed the U.S. Internal Revenue Code. Such changes include a reduction in the corporate tax rate and limitations on certain corporate deductions and credits, among other changes. Certain of these changes could have a negative impact on our business. In addition, adverse changes in the financial outlook of our operations or changes in tax law could lead to changes in our valuation allowances against deferred tax assets on our consolidated balance sheets, which could materially affect our results of operations.

Risks Relating to Government Regulation

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

We do not have the necessary approval to market or sell aNK platform products in the U.S. or any foreign market. Before marketing aNK platform product candidates, we must successfully complete extensive preclinical studies and clinical trials and rigorous regulatory approval procedures. We cannot offer assurances that we will apply for or obtain the necessary regulatory approval to commercialize aNK platform 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 haNK, taNK and t-haNK 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, haNK, taNK and t-haNK cells are produced in small-scale cell culture systems and we may be unable to adapt the production method to large-scale production systems. In addition, patients participating in the trials may die before completion of the clinical trial or suffer adverse medical effects unrelated to treatment with haNK, taNK and t-haNK 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 platform product is novel, and cell-based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like our aNK platform products. This inexperience may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our aNK platform products. In addition, the following factors may impede or delay our ability to obtain timely regulatory approvals, if at all:

- potential delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- our failure to obtain sufficient enrollment in our clinical trials or participants may fail to complete our clinical trials;

- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- regulators may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain regulatory approval;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may need to delay or suspend one or more trials until we complete additional financing transactions or otherwise receive adequate funding;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may be delayed;
- our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or institutional review boards to suspend or terminate trials;
- regulatory authorities may suspend or withdraw their approval of a product or impose restrictions on its distribution;
- 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 and manufacturing processes to demonstrate consistent safety, purity, identity, and potency standards;
- a decision by us, institutional review boards, or regulators to suspend or terminate our clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants 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 regulators find us not to be in compliance with applicable regulatory requirements;
- our ability to produce sufficient quantities of haNK, taNK or t-haNK 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 haNK, taNK and t-haNK 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 haNK, taNK and t-haNK cells.

Even if we obtain regulatory approvals for aNK related platform products, 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, our aNK platform products, and our manufacturing facilities will be subject to continual regulatory review, including periodic unannounced inspections, by the FDA and other U.S. 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 platform 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 haNK, taNK and t-haNK 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 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 platform products, 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, haNK, taNK and t-haNK 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 further approvals. This may harm our business and results of operations or cause our reputation in the market place to suffer or subject us to lawsuits, including class action suits.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects or adverse events caused by such products, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may withdraw approvals of such product or require additional warnings on the label;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-approval studies;
- we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects.

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 U.S., 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 U.S. 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 U.S. a drug or biologic for a disease or condition will be recovered from sales in the U.S. 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 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 product candidates, but exclusive marketing rights in the U.S. 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 U.S. 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. In addition, 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 U.S., 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 U.S. 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 U.S. 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 U.S., 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 U.S. 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 U.S. federal False Claims Act and the U.S. 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.

The ACA has been modified and amended recently, including the elimination of the individual mandate that individuals purchase healthcare insurance. Furthermore, the current presidential administration and Congress may continue to attempt broad sweeping changes to the current health care laws. We face uncertainties that might result from modification or repeal of any of the provisions of the ACA, including as a result of current and future executive orders and legislative actions. The impact of those changes on us and potential effect on the pharmaceutical and biotechnology industry as a whole is currently unknown. However, any changes to the ACA are likely to have an impact on our results of operations, and may have a material adverse effect on our results of operations. We cannot predict what other healthcare programs and regulations will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation in the U.S. may have on our business.

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. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

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 U.S. 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 have used 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 IPO 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. If such 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.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the FDA, SEC and other government agencies on which our operations may rely is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could potentially impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We may be, or may become, subject to data protection laws and regulations, and our failure to comply with such laws and regulations could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

The E.U. has adopted data protection laws and regulations which may apply to us in certain circumstances, or in the future. These laws, which impose significant compliance obligations, are commonly known as the General Data Protection Regulation, or GDPR. The GDPR, which is wide-ranging in scope and applicability, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third party processors in connection with the processing of personal data, including clinical trials. The GDPR also imposes strict rules on the transfer of personal data out of the E.U. to the U.S., provides an enforcement authority, and imposes large penalties for noncompliance, including the potential for fines of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Implementation of the GDPR, as applicable to us, will increase our responsibility and liability in relation to personal data that we process, including in clinical trials, and we may in the future be required to put in place additional mechanisms to ensure compliance with the GDPR, which could divert management's attention and increase our cost of doing business. In addition, other new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data protection in the U.S., the E.U. and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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 contractual agreements, including 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 haNK, taNK and t-haNK 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 haNK, taNK and t-haNK 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. 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 U.S. 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.

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 U.S., 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 U.S. had previously enacted and implemented wide-ranging patent reform legislation (e.g., the Leahy-Smith America Invents Act in September 2011) and are currently considering additional legislation that may materially impact our ability to obtain or enforce our patents. Further, recent U.S. Supreme Court rulings and recent decisions from the United States Court of Appeals for the Federal Circuit 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.

In addition, changes to U.S. patent laws provide additional procedures for third parties to challenge the validity of issued patents based on patent applications filed after March 15, 2013. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our current or future product candidates is challenged, then it could threaten our ability to commercialize our current or future product candidates and could threaten our ability to prevent competitive products from being marketed. Further, if we encounter delays in our clinical trials, the period of time during which we could market our current or future product candidates under patent protection would be reduced. Since U.S. patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates, or (ii) invent any of the inventions claimed in our patents or patent applications. Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party or instituted by the U.S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a "first-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application with the USPTO 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. The change to "first-to-file" from "first-to-invent" is one of the changes to the U.S. patent laws resulting from the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011.

Among some of the other significant changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and provide 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 U.S. 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. It is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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 our 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. For example, we believe that certain companies, including at least one in China, may be using our NK-92 cell line without our permission. 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, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. The requirements for patentability may differ in certain countries, particularly developing countries. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. and in some cases, may even force us to grant a compulsory license to competitors or other third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement on infringing activities is inadequate or not as strong as that in the U.S. 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.

Patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant and, in addition, may be challenged before national courts at any time. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold, license or pursue with respect to our product candidates is threatened, it could threaten our ability to commercialize our product candidates.

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 or biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial 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.

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 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 U.S.

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 U.S., 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 U.S., 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. The Leahy-Smith Act introduced 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.

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 and related platform product cell therapies, 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 obligation to pay royalties to Dr. Klingemann under the license agreement, as amended, runs until the expiration of the underlying patents and the license agreement may be terminated earlier by either party for material breach. Under the license agreement, we have the right to enforce the licensed patents. Our license agreement with Rush University Medical Center terminated on the 12th anniversary of our first payment of royalties, at which point the license was deemed a perpetual, irrevocable, fully paid royalty-free, exclusive license.

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 and confidentiality agreements, including those with our employees and consultants, 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. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential intellectual property. 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 U.S. 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. Also, third parties, including our competitors, may independently develop substantially equivalent proprietary information and technologies or otherwise lawfully gain access to our trade secrets and other confidential information. In such a case, we would have no right to prevent such third parties from using such proprietary information or technologies to compete with us, which could harm 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, including our competitors or potential competitors. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed intellectual property, including trade secrets, confidential information, or other proprietary information, of these third parties or our employees' or consultants' or independent contractors' former or other 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.

Risks Relating to Our Common Stock

****Our Chairman and CEO 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, 2020, our Chairman and CEO, Patrick Soon-Shiong, M.D., and entities affiliated with him, collectively own approximately 67.2% of the outstanding shares of our common stock. Additionally, Dr. Soon-Shiong holds vested options to purchase an aggregate of 900,000 additional shares of our common stock, which would give him and his affiliates ownership of approximately 67.5% of our outstanding shares of common stock if they were 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.

The market price of our stock may fluctuate significantly, and investors may have difficulty selling their shares.

Prior to our IPO in July 2015, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Global Select Market, or Nasdaq, 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. 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;
- the perception of our clinical trial results by retail investors, which investors may be subject to the influence of information provided by third party investor websites and independent authors distributing information on the internet; 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 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, 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 addition, as of March 31, 2020 our chairman and CEO, Dr. Soon-Shiong, and his affiliates beneficially owned approximately 67.5% of our outstanding shares of common stock. Sales of stock by Dr. Soon-Shiong and his affiliates could have a material adverse effect on the trading price of our common stock.

Certain holders of approximately 46.2 million shares of our common stock 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.

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 compliance initiatives and corporate governance practices, including maintaining an effective system of internal control over financial reporting.

As a public company listed in the U.S., 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 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 U.S., 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,” and if we are not a smaller reporting company at that time, 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.

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. 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, 2019, or for any other period. Accordingly, no such opinion was expressed in 2019. For the year ending December 31, 2020, we may be subject to the auditor attestation requirements of Section 404 of Sarbanes-Oxley. There can be no assurance that we will not discover deficiencies or a material weakness in our internal control over financial reporting or that our auditor will agree with management’s assessment of our internal control over financial reporting.

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.

If a restatement of our financial statements were to occur, our shareholders’ confidence in the company’s financial reporting in the future may be affected, which could in turn have a material adverse effect on our business and stock price.

If any material weaknesses in our internal control over financial reporting are discovered or occur in the future, our 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 any future 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 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 CEO, 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. Our board of directors is currently comprised of a majority of independent directors. In addition, although not required by the rules of Nasdaq, in August 2019, our board of directors established a nominating and corporate governance committee comprised of three directors, two of which are independent. 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 a “smaller reporting company,” and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies could make our common stock 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 IPO, or December 31, 2020, although, if we have more than \$1.07 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 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. Even after we no longer qualify as an emerging growth company, we may, under certain circumstances, still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. 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, 2019 we had U.S. federal, state and foreign NOLs of approximately \$291.8 million, \$255.7 million and \$0.2 million, respectively, some of which begin to expire in various years starting with 2022, if not utilized. As of December 31, 2019, we also had federal and state research and development tax credit carryforwards of approximately \$8.5 million and \$5.7 million, respectively. These net operating loss and research and development tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change 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. We completed an IRC Section 382/383 analysis through March 2019 regarding the limitation of net operating loss and research and development credit carryforwards. The analysis concluded that the federal and state carryforwards associated with the NOLs were reduced by the amount of tax attributes estimated to expire during their respective carryforward periods.

Since we will need to raise substantial additional funding to finance our operations, we may experience further ownership changes in the future, some of which may be outside of our control. Limits on our ability to use our pre-change NOLs or credits to offset U.S. federal taxable income could potentially result in increased future tax liability to us if we earn net taxable income in the future. In addition, under the legislation commonly referred to as the Tax Cuts and Jobs Act of 2017, or TCJA, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, the amount of NOLs generated in taxable periods beginning after December 31, 2017, that we are permitted to deduct in any taxable year beginning after December 31, 2020 is limited to 80% of our taxable income in such year, where taxable income is determined without regard to the NOL deduction itself. The TCJA, as modified by the CARES Act, permits a five-year carryback for NOLs arising in taxable years beginning after December 31, 2017 and before January 1, 2021 but eliminates the carryback for NOLs arising in taxable years thereafter while allowing post-2017 unused NOLs to be carried forward indefinitely. Similar rules may apply under state tax laws.

We are a U.S.-based company subject to tax in the U.S. and in Korea. Significant judgment is required in determining our global provision for income taxes, deferred tax assets or liabilities, and in evaluating our tax positions on a worldwide basis. While we believe our tax positions are consistent with the tax laws in the jurisdictions in which we conduct our business, it is possible that these positions may be overturned by jurisdictional tax authorities, which may have a significant impact on our global provision for income taxes.

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 CEO (who with members of his immediate family and entities affiliated with him owned approximately 67.2% of our common stock as of March 31, 2020) 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 acquirers 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 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 Sales of Unregistered Securities**

None.

(b) Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

The documents listed below are incorporated by reference or are filed with this Quarterly Report, in each case as indicated therein (numbered in accordance with Item 601 of Regulation S-K).

Exhibit Number	Description
10.1*	First Amendment to the July 1, 2019 Letter Agreement between the Company and Immuno-Oncology Clinic, Inc., dated March 31, 2020.
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.

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.

Date: May 11, 2020

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

Date: May 11, 2020

By: /s/ Sonja Nelson
Sonja Nelson
Chief Financial Officer
(Principal Financial and Accounting Officer)

March 31, 2020

Immuno-Oncology Clinic, Inc.
2040 E. Mariposa Avenue
El Segundo California 90245

Ladies and Gentlemen:

Reference is made to that certain letter agreement made effective as of July 1, 2019 by and between Immuno-Oncology Clinic, Inc. (the "Clinic") and NantKwest, Inc. ("Nant") (the "Letter Agreement"). Tara Seery, MD and Chaitali Nangia, MD (together, "Investigators"), while not parties hereto, are nevertheless executing this Amendment to the Letter Agreement (the "Amendment") to acknowledge that they have read and understood this Amendment in its entirety and agree to comply with the terms and conditions hereof.

In consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1. Section 2(a) of the Letter Agreement is deleted in its entirety and replaced with the below:

(a) Payment of Research Fee. In consideration of the Services to be performed, Nant hereby agrees to pay to the Clinic during the Initial Term (as defined below) a research fee (the "Research Fee") of up to Seven Million Five Hundred Thousand Dollars (\$7,500,000), payable as follows: (i) Three Million Seven Hundred Fifty Thousand Dollars (\$3,750,000) shall be paid as soon as practicable but in any event no later than ten (10) business days of the Effective Date; (ii) One Million Eight Hundred Seventy Five Thousand Dollars (\$1,875,000) shall be due and payable on October 1, 2019; and (iii) a conditional payment of One Million Eight Hundred Seventy Five Thousand Dollars (\$1,875,000) shall be due and payable on the later of (x) January 1, 2020 and (y) such time, if any, that the payments made pursuant to Sections 2(a)(i) and 2(a)(ii) hereunder have been earned by the Clinic through the performance of Services. The parties acknowledge and agree that, to the extent the fair market value of Services performed by the Clinic during the Initial Term is less than the amounts paid by Nant pursuant to Sections 2(a)(i) and 2(a)(ii) hereunder, then Nant shall have no further payment obligation.

2. All capitalized terms used herein and not defined shall have the same meaning as such capitalized terms in the Letter Agreement.
3. If there are any conflicts between the Letter Agreement and this Amendment, this Amendment shall be controlling.

[SIGNATURE PAGE TO FOLLOW]

Please kindly countersign below to confirm your agreement with the foregoing terms and conditions.

Sincerely,

NantKwest, Inc.

By: /s/ Steven C. Yang
Name: Steven Yang
Title: General Counsel

ACKNOWLEDGED AND AGREED:

Immuno-Oncology Clinic, Inc.

By: /s/ Leonard Sender
Name: Leonard Sender
Title: President

INVESTIGATORS:

Tara Seery, M.D.

/s/ Tara Seery
Signature

Chaitali Nangia, M.D.

/s/ Chaitali Nangia
Signature

**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Patrick Soon-Shiong, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 11, 2020

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

**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Sonja Nelson, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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 11, 2020

By: /s/ Sonja Nelson

Sonja Nelson

Chief Financial Officer

(Principal Financial and Accounting Officer)

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO 18 U.S.C. § 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY 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 10-Q for the quarter ended March 31, 2020 (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 11, 2020

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

**CERTIFICATION PURSUANT TO 18 U.S.C. § 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-
OXLEY ACT OF 2002**

I, Sonja Nelson, 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 10-Q for the quarter ended March 31, 2020 (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 11, 2020

By: */s/ Sonja Nelson*

Sonja Nelson

Chief Financial Officer

(Principal Financial and Accounting Officer)